

# Exhibit 2

1 IN THE UNITED STATES DISTRICT COURT  
2 FOR THE DISTRICT OF NEW JERSEY  
3 CAMDEN VICINAGE  
- - -

4 IN RE: VALSARTAN, : MDL NO. 2875  
5 LOSARTAN, AND IRBESARTAN: CIVIL ACTION NO.  
6 PRODUCTS LIABILITY : 19-2875  
7 LITIGATION : (RBK/JS)

8 \_\_\_\_\_  
9 THIS DOCUMENT APPLIES : HONORABLE  
10 TO ALL CASES : ROBERT B. KUGLER  
11 - - -  
12 FEBRUARY 8, 2023  
13 Remote Videotape Deposition,  
14 taken via Zoom, of ALI AFNAN, Ph.D.,  
15 commencing at 9:23 a.m., on the above  
16 date, before Amanda Maslynsky-Miller,  
17 Realtime Reporter and Certified Court  
18 Reporter in and for the State of New  
19 Jersey.

20 - - -  
21 GOLKOW LITIGATION SERVICES, INC.  
22 877.370.3377 ph| 917.591.5672 fax  
23 deps@golkow.com  
24

<p style="text-align: right;">Page 2</p> <p>1 APPEARANCES:</p> <p>3 MAZIE SLATER KATZ &amp; FREEMAN LLC BY: ADAM M. SLATER, ESQUIRE BY: CHRISTOPHER J. GEDDIS, ESQUIRE 103 Eisenhower Parkway 2nd Floor Roseland, New Jersey 07068 (973) 228-9898 aslater@mazieslatter.com cgeddiss@mazieslatter.com Representing the Plaintiff</p> <p>10 RIVERO MESTRE LLP BY: JORGE A. MESTRE, ESQUIRE BY: ZALMAN KASS, ESQUIRE BY: AMANDA L. FERNANDEZ, ESQUIRE 2525 Ponce de Leon Boulevard Suite 1000 Miami, Florida 33134 (305) 445-2500 jmestre@riveromestre.com zkass@riveromestre.com afernandez@riveromestre.com Representing the Plaintiff</p> <p>18 FARR FARR EMERICH HACKETT &amp; HOLMES, P.A. BY: GEORGE T. WILLIAMSON, ESQUIRE 99 Nesbit Street Punta Gorda, Florida 33950 (941) 639-1158 gwilliamson@farr.com Representing the Plaintiff</p>	<p style="text-align: right;">Page 4</p> <p>1 APPEARANCES: (Continued)</p> <p>3 WALSH PIZZI O'REILLY FALANGA LLP BY: CHRISTINE I. GANNON, ESQUIRE Three Gateway Center 100 Mulberry Street 15th Floor Newark, New Jersey 07102 (973) 757-1100 cgannon@walsh.law Representing Teva Pharmaceuticals Industries Limited</p> <p>10 GREENBERG TRAURIG LLP BY: BRIAN RUBENSTEIN, ESQUIRE 1717 Arch Street Suite 400 Philadelphia, Pennsylvania 19103 (215) 988-7800 rubensteinb@gtlaw.com Representing Teva Pharmaceuticals Industries Limited</p> <p>18 BUCHANAN INGERSOLL &amp; ROONEY PC BY: CHRISTOPHER B. HENRY, ESQUIRE Carillon Tower 227 West Trade Street Suite 600 Charlotte, North Carolina 28202 (704) 444-3300 christopher.henry@bipc.com Representing Albertson's LLC</p>
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1	2	3	4	5	6
1 APPEARANCES: (Continued)			E X H I B I T S		
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5	Testimony of: ALI AFNAN, Ph.D.				
6	By Mr. Slater	12			
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9					
10	E X H I B I T S				
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12	NO.	DESCRIPTION	PAGE	NO.	DESCRIPTION
13	Afnan-1	No Bates		Afnan-12	No Bates
14		Defendants' Responses and			10/25/06 Impurities in
15		Objections to Plaintiffs'			New Drug Substances
16		Notice to Take Videotaped			Q3A(R2)
17		Deposition (ECF NO. 2258)	17		306
18	Afnan-2	No Bates		Afnan-13	No Bates
19		12/23/22 Expert Report of			Guidance for Industry
20		Ali Afnan, Ph.D.	41		Genotoxic and Carcinogenic
21	Afnan-3	No Bates			Impurities in Drug Substances
22		1/11/23 Expert Report of			And Products: Recommended
23		Ali Afnan, Ph.D.	43		Approaches
24	Afnan-4	PRINSTON00077339-7344		Afnan-14	ZHP00662283-2309
		11/29/18 Letter,			Investigation Regarding an
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					Good Manufacturing Practice
					Guidance for Active
					Pharmaceutical Ingredients
				Afnan-16	ZHP01721348
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2 DEPOSITION SUPPORT INDEX  
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5 Direction to Witness Not to Answer  
6 Page Line Page Line Page Line  
7 149 21  
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10 Request for Production of Documents  
11 Page Line Page Line Page Line  
12 None  
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15 Stipulations  
16 Page Line Page Line Page Line  
17 11 1  
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19  
20 Question Marked  
21 Page Line Page Line Page Line  
22 None  
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24

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1 - - -  
2 (It is hereby stipulated and  
3 agreed by and among counsel that  
4 sealing, filing and certification  
5 are waived; and that all  
6 objections, except as to the form  
7 of the question, will be reserved  
8 until the time of trial.)  
9 - - -

10 VIDEO TECHNICIAN: Good  
11 morning. We are now on the  
12 record. My name is Phillip Todd,  
13 I'm a videographer for Golkow  
14 Litigation Services. Today's date  
15 is February 8th, 2023, and the  
16 time is 9:32 a.m.  
17

18 This remote video deposition  
19 is being held in the matter of  
20 Valsartan, Losartan and Irbesartan  
21 Products Liability Litigation in  
22 the United States District Court,  
23 District of New Jersey. The  
24 deponent is Dr. Ali Afnan.

deposition are appearing remotely and have agreed to the witness being sworn in remotely.

Due to the nature of remote reporting, please pause briefly before speaking to ensure all parties are heard completely.

Counsel's appearances will be noted on stenographic record. The court reporter, Amanda Miller, will now swear in the witness.

ALI AFNAN, Ph.D., after having been duly sworn, was examined and testified as follows:

## EXAMINATION

BY MR. SLATER:

Q. Good morning, Dr. Afnan.

A. Good morning.

Q. I'm Adam Slater, I'm going

take your deposition. How are you?

1

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<sup>1</sup> much.

<sup>2</sup> Q. Great. Have you been  
<sup>3</sup> deposed before?

4 A. No.

5 Q. You understand you must tell  
6 the truth in response to every question  
7 you're asked today?

<sup>8</sup> A. Yes.

9           Q. If you're asked a question  
10 and you don't understand, for any reason,  
11 and you don't feel you can answer it  
12 truthfully or correctly, please tell the  
13 questioner and we'll refine the question  
14 so that you can understand it and that  
15 way you can then answer it, okay?

<sup>16</sup> A. Will do.

17 Q. If counsel objects, let the  
18 counsel say whatever they need to say,  
19 and then you'll most likely be told to go  
20 ahead and answer.

<sup>21</sup> But wait until the objection  
<sup>22</sup> is stated, okay?

<sup>23</sup> A. Thank you.

<sup>24</sup> Q. When did you first become

<p>1 aware that valsartan manufactured by ZHP      2 contained NDMA and NDEA?      3 A. I think the very first time      4 I became aware of it when -- is when I      5 was approached to act as an expert      6 witness.      7 Q. What was that date?      8 A. Sometime early October. I      9 don't have the exact date.      10 Q. Before that date, you were      11 not aware of the fact that the valsartan      12 manufactured by ZHP contained NDMA and      13 NDEA?      14 A. I -- no.      15 Q. Were you aware of the recall      16 of valsartan before that time that you      17 were first approached for this case?      18 A. No.      19 Q. Had you ever heard of NDMA      20 before you were approached regarding this      21 case?      22 A. I had heard of nitrosamines,      23 yes.      24 Q. In what context?</p>	<p>Page 14</p> <p>1 pharma were having lunch together?      2 A. No. As I said, it's      3 ex-colleagues. It's a group of us who      4 have retired, who have left FDA. We were      5 meeting -- we meet every now and then.      6 Q. You said they were ex --      7 I'll rephrase.      8 You said they were pharmacy      9 executives. Did they also work at the      10 FDA, those same people?      11 A. No, no, no. They were not      12 executives, they were employees of      13 pharma, who have retired from pharma, and      14 also ex-FDA employees; people that I used      15 to work with.      16 Q. So that was just an informal      17 conversation at a lunch?      18 A. That was purely an informal,      19 by the way, have you heard of, yes.      20 Q. When did that occur?      21 A. Maybe summer of last year.      22 Q. Summer of 2022?      23 A. No, I don't remember the      24 exact date. I'm just saying maybe summer</p>
<p>1 A. Discussions with      2 ex-colleagues about presence of NDMA in      3 certain products, but not specific to      4 which product.      5 Q. When was that? Are you      6 talking about before you were retained in      7 this case?      8 A. It's before I was retained      9 in this case, yes.      10 Q. And what was the context      11 where you spoke to colleagues about NDMA?      12 A. It was just that, you know,      13 NDMA was present in certain products.      14 Again, not specifically mentioned, except      15 that it was in Metformin, because both of      16 us were taking Metformin at that time.      17 Q. And who was this colleague      18 that you spoke to about this?      19 A. It's -- it was actually at      20 lunch with a group of ex-colleagues who      21 are pharma executives or pharma employees      22 and FDA employees.      23 Q. So you were at a lunch where      24 people from the FDA and people from</p>	<p>Page 15</p> <p>1 of 2022.      2 Q. You said summer of last      3 year, that's why I asked --      4 A. Yes.      5 Q. -- if it was 2022.      6 A. Yes.      7 Q. If I understand correctly,      8 in your work that you had done before you      9 were approached for this case, you never      10 specifically addressed nitrosamines, NDMA      11 or NDEA; is that correct?      12 A. Correct.      13 MR. SLATER: Let's mark as      14 Exhibit-1 the response to the      15 deposition notice.      16 - - -      17 (Whereupon, Exhibit Afnan-1,      18 No Bates, Defendants' Responses      19 and Objections to Plaintiffs'      20 Notice to Take Videotaped      21 Deposition (ECF NO. 2258), was      22 marked for identification.)      23 - - -      24 MR. SLATER: We can put that</p>

<p>1 on the screen.      2 MS. DAVIDSON: So I just      3 want to make sure I understand.      4 Are we going to be having that for      5 everyone to see on the screen?      6 MR. SLATER: That's why I      7 said put it on the screen.      8 MS. DAVIDSON: Just the      9 other day you had a different      10 approach you wanted to take, so I      11 wanted to make sure I understood.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. Doctor, do you see the      14 exhibit -- the document we put up as      15 Exhibit-1 on the screen?</p> <p>16 A. Yes.</p> <p>17 Q. Have you seen this document      18 before?</p> <p>19 A. If you scroll down, I will      20 be able to tell you yes or no. I see      21 only the top of the page.</p> <p>22 Thank you.</p> <p>23 Q. You can see now the first      24 page. It's titled, Defendants' Responses</p>	<p>Page 18</p> <p>1 in the deposition notice to the lawyers      2 who hired you?      3 A. Yes.      4 MS. DAVIDSON: Dr. Afnan, I      5 wanted to object to that question,      6 and you did not give me time. So      7 please make sure when Adam asks      8 you a question, I know Adam talks      9 very fast, and that encourages      10 everyone around him to talk very      11 fast, but it doesn't give -- I am      12 not fast. It doesn't give me time      13 to object.      14 So I do object to that      15 question.      16 And please make sure that      17 you allow me time in this      18 deposition to object.      19 THE WITNESS: Sure. Sorry.      20 Will do.      21 MR. SLATER: Chris, let's go      22 to the end, to Number 17, please.      23 Maybe we can make it a little      24 bigger. Perfect.</p>
<p>1 and Objections to Plaintiffs' Notice to      2 Take Videotape Deposition.</p> <p>3 A. Yes.</p> <p>4 Q. Have you seen this document      5 before?</p> <p>6 A. Yes.</p> <p>7 Q. Did you see the deposition      8 notice?</p> <p>9 A. I think so, yes.</p> <p>10 MS. DAVIDSON: I think Ali,      11 not being a lawyer, might not know      12 what a deposition notice is. So      13 if you want to ask if he's seen      14 it, I suggest you show it to him.</p> <p>15 MR. SLATER: That's all      16 right. He just said he saw it.</p> <p>17 THE WITNESS: No, I -- this      18 is what I have seen.</p> <p>19 BY MR. SLATER:</p> <p>20 Q. Great. The questions are      21 all on this, too. So we're good.</p> <p>22 Okay. Did you go through      23 each of the requests and attempt to      24 provide the documents that were requested</p>	<p>Page 19</p> <p>1 BY MR. SLATER:</p> <p>2 Q. Looking at Number 17, it      3 requested, Any cGMP guidance, rule,      4 protocol or procedure, drafted in whole      5 or in part by Dr. Afnan, related to the      6 development or manufacture of API or      7 finished dose and/or with regard to      8 genotoxic or other impurities in API or      9 finished dose.</p> <p>10 Do you see that?</p> <p>11 A. Yes, I see that.</p> <p>12 Q. In response, we were told      13 that you were involved in the development      14 of FDA's process analytical technology      15 guidance in -- dated 2003, process      16 validation guidance 2011, and guidance      17 for industry, Q8 pharmaceutical      18 development, 2006, correct?</p> <p>19 MS. DAVIDSON: Adam, I don't      20 see that. Is that --</p> <p>21 MR. SLATER: It's in the      22 response in the first paragraph of      23 the response that you guys wrote.</p> <p>24 MS. DAVIDSON: Oh, I see</p>

<p>1 where you are. If you can point 2 to where you're reading on the 3 page, it would be helpful.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. Do you see where I just 6 read, Doctor?</p> <p>7 A. What you -- yes, I do.</p> <p>8 Q. Did you ever draft, in whole 9 or in part, any other guidances, rules, 10 protocols or procedures related to the 11 development or manufacture of API or 12 finished dose and/or with regard to 13 genotoxic or other impurities in API or 14 finished dose?</p> <p>15 MS. DAVIDSON: Adam, if you 16 could possibly talk a little 17 slower. I can't --</p> <p>18 MR. SLATER: I'm sorry, 19 I'm -- I'm doing the best I can.</p> <p>20 BY MR. SLATER:</p> <p>21 Q. Are there any others, 22 Doctor?</p> <p>23 A. No.</p> <p>24 Q. Do you agree that cGMP is an</p>	<p>Page 22</p> <p>1 BY MR. SLATER:</p> <p>2 Q. Do you agree with me that 3 ZHP was required to comply with cGMP at 4 all times -- at all times in the 5 development and manufacture of valsartan?</p> <p>6 MS. DAVIDSON: I'm going to 7 object again. And, also, I 8 believe it was asked and answered.</p> <p>9 THE WITNESS: I did actually 10 answer it.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. Yes or no, please.</p> <p>13 MS. DAVIDSON: Adam, you 14 know very well that he's not 15 required to give you yes or no. 16 He's allowed to answer the 17 question as he deems fit and to 18 provide whatever context he thinks 19 is necessary.</p> <p>20 If I understand this 21 question, I believe we've been 22 down this road in this MDL 23 proceeding.</p> <p>24 BY MR. SLATER:</p>
<p>1 obligation -- rephrase.</p> <p>2 Do you agree that compliance 3 with cGMP is an obligation of a 4 pharmaceutical manufacturer like ZHP?</p> <p>5 MS. DAVIDSON: Objection.</p> <p>6 BY MR. SLATER:</p> <p>7 Q. Yes or no?</p> <p>8 MS. DAVIDSON: I'm going to 9 object to that question. If that 10 was a second question, I'm 11 objecting again. I think it's 12 vague.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. Can you answer the question, 15 please, Doctor?</p> <p>16 A. So --</p> <p>17 MS. DAVIDSON: Adam, give 18 him a minute. Come on.</p> <p>19 THE WITNESS: So cGMPs are a 20 minimal requirement for operation 21 which industry pharma companies 22 are expected to be aware of and to 23 apply to their processes and their 24 practices.</p>	<p>Page 23</p> <p>1 Q. Please answer the question, 2 Doctor.</p> <p>3 A. GMPs specify what needs to 4 be done and not how the things are to be 5 done in a pharma company; and ZHP adhered 6 to the GMPs.</p> <p>7 Q. Now I'm going to ask the 8 question again.</p> <p>9 I didn't ask you any of that 10 other things that you're talking about. 11 So our deposition will go much more 12 smoothly if I ask you a direct question 13 to just answer it directly and not talk 14 about other things. So I would 15 appreciate it if you could try to do 16 that, please.</p> <p>17 Was ZHP required to comply 18 with cGMPs at all times during the 19 development and manufacture of the 20 valsartan that they manufactured and 21 sold?</p> <p>22 MS. DAVIDSON: I'm going to 23 object again. At this point I 24 think you're badgering the</p>

<p>1 witness.</p> <p>2 THE WITNESS: So I have</p> <p>3 answered the question. And I</p> <p>4 can't not give a dimension to my</p> <p>5 response.</p> <p>6 However, if you say, were</p> <p>7 they required -- was ZHP required</p> <p>8 to apply it, the GMPs, my -- I</p> <p>9 have to make a lot of assessments</p> <p>10 to say -- to answer that question.</p> <p>11 Again, I'll repeat, GMPs are</p> <p>12 a list of what-to-dos, not</p> <p>13 how-to-dos, and ZHP adhered to the</p> <p>14 GMPs.</p> <p>15 BY MR. SLATER:</p> <p>16 Q. I didn't ask you if they</p> <p>17 adhered. I didn't ask you if it's a</p> <p>18 how-to. I didn't ask you any of those</p> <p>19 questions.</p> <p>20 So I thought this would be</p> <p>21 the easiest question of the deposition.</p> <p>22 So I'm going to try it again.</p> <p>23 Do you agree with me that</p> <p>24 ZHP was required to comply with cGMPs in</p>	<p>Page 26</p> <p>1 question to ask if ZHP was required to</p> <p>2 comply with cGMPs in the development and</p> <p>3 manufacture of valsartan; is that your</p> <p>4 testimony?</p> <p>5 MS. DAVIDSON: I'm sorry.</p> <p>6 Objection.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. Please answer.</p> <p>9 A. So the --</p> <p>10 MS. DAVIDSON: Hold on.</p> <p>11 You're mischaracterizing this</p> <p>12 testimony. And, also, every time</p> <p>13 I object you then ask a second</p> <p>14 question so that I have to object</p> <p>15 again.</p> <p>16 So I suggest that after I</p> <p>17 object, Dr. Afnan knows that he's</p> <p>18 supposed to answer a question,</p> <p>19 unless I instruct him not to</p> <p>20 answer. So I don't think it's</p> <p>21 helpful to badger him after I</p> <p>22 object, pressuring him to answer</p> <p>23 the question. He knows there's a</p> <p>24 question pending.</p>
<p>1 the development and manufacture of the</p> <p>2 valsartan API that it manufactured?</p> <p>3 MS. DAVIDSON: Objection</p> <p>4 again. Asked and answered.</p> <p>5 Vague. And at this point,</p> <p>6 badgering the witness.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. It's a yes-or-no question,</p> <p>9 Doctor.</p> <p>10 MS. DAVIDSON: Again, I</p> <p>11 believe I stated this two minutes</p> <p>12 ago, but I'll state it again. He</p> <p>13 is not required to answer yes or</p> <p>14 no if he does not feel that yes or</p> <p>15 no is an adequate answer to the</p> <p>16 question. There's no thought</p> <p>17 control here.</p> <p>18 I'm sorry, Dr. Afnan.</p> <p>19 THE WITNESS: A yes or no</p> <p>20 does not actually address the</p> <p>21 question. I think the question is</p> <p>22 vague.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. You think it's a vague</p>	<p>Page 27</p> <p>1 And then it's unclear to me,</p> <p>2 when you badger him again, whether</p> <p>3 I need to object again for the</p> <p>4 record.</p> <p>5 Do you want the court</p> <p>6 reporter to read back the</p> <p>7 question, Dr. Afnan, since we</p> <p>8 distracted you with our</p> <p>9 back-and-forth?</p> <p>10 THE WITNESS: Yes, please.</p> <p>11 - - -</p> <p>12 (Whereupon, the court</p> <p>13 reporter read the following part</p> <p>14 of the record:</p> <p>15 "Question: You think it's</p> <p>16 a vague question to ask" --)</p> <p>17 - - -</p> <p>18 MR. SLATER: I'm just going</p> <p>19 to state for the record that I</p> <p>20 think that defense counsel is</p> <p>21 obstructing the deposition.</p> <p>22 I'm going to now continue.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. Dr. Afnan, are you saying</p>

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<sup>1</sup> that my question is vague when I ask you  
<sup>2</sup> if ZHP was required to comply with cGMPs  
<sup>3</sup> in the development and manufacture of  
<sup>4</sup> valsartan?

<sup>5</sup> MS. DAVIDSON: Wait a  
<sup>6</sup> minute. Adam, are you taking back  
<sup>7</sup> the last question that I'm having  
<sup>8</sup> the court reporter read back?

<sup>9</sup> MR. SLATER: I'm not  
<sup>10</sup> going -- I'm not going to go  
<sup>11</sup> back-and-forth with you. You're  
<sup>12</sup> eating up my time already. I'm  
<sup>13</sup> not doing this with you.

<sup>14</sup> So I'm going to continue my  
<sup>15</sup> deposition.

<sup>16</sup> MS. DAVIDSON: So I assume  
<sup>17</sup> that question was stricken.

<sup>18</sup> BY MR. SLATER:

<sup>19</sup> Q. Please answer.

<sup>20</sup> A. The reason I believe your  
<sup>21</sup> answer is vague is -- your question is  
<sup>22</sup> vague is because this is not a simple yes  
<sup>23</sup> or no. It depends what the definition of  
<sup>24</sup> cGMPs are, because, as I said, cGMPs are

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<sup>1</sup> guidance Q7. For drug product  
<sup>2</sup> manufacturers, it's defined in 210 and  
<sup>3</sup> 211 of the code of federal regulations.

<sup>4</sup> Again, those are the  
<sup>5</sup> what-to-dos and not the how-to-dos.

<sup>6</sup> Q. The how-to-do is pursuant to  
<sup>7</sup> internal standard operating procedures  
<sup>8</sup> that are put into place by the firm; is  
<sup>9</sup> that what you're telling me?

<sup>10</sup> A. Yes.

<sup>11</sup> Q. Are you saying that ZHP was  
<sup>12</sup> only required to comply with its own  
<sup>13</sup> internal standard operating procedures  
<sup>14</sup> with regard to cGMP and was not required  
<sup>15</sup> to comply with ICH or other outside  
<sup>16</sup> sources of cGMP guidance?

<sup>17</sup> MS. DAVIDSON: Objection.

<sup>18</sup> Mischaracterizes the witness's  
<sup>19</sup> testimony.

<sup>20</sup> THE WITNESS: That's not  
<sup>21</sup> what I said.

<sup>22</sup> BY MR. SLATER:

<sup>23</sup> Q. At all times that --  
<sup>24</sup> rephrase.

<sup>1</sup> a list of what-to-dos as stipulated by  
<sup>2</sup> the Food and Drug Administration.

<sup>3</sup> How those are effectively  
<sup>4</sup> put into practice is done through the  
<sup>5</sup> procedures of the firm.

<sup>6</sup> Q. And when the firm, then,  
<sup>7</sup> puts those principles into effect, those  
<sup>8</sup> standard operating procedures and  
<sup>9</sup> internal procedures become requirements  
<sup>10</sup> under cGMP, correct?

<sup>11</sup> MS. DAVIDSON: Objection.

<sup>12</sup> THE WITNESS: That's a  
<sup>13</sup> circular argument. They don't  
<sup>14</sup> become requirements under cGMP,  
<sup>15</sup> they become, effectively, the  
<sup>16</sup> practicing standards of the firm.  
<sup>17</sup> And the firm can change those as  
<sup>18</sup> well. There is a procedure for  
<sup>19</sup> changing those. They are not, you  
<sup>20</sup> know, written once and for all.

<sup>21</sup> BY MR. SLATER:

<sup>22</sup> Q. How do you define cGMP?

<sup>23</sup> A. It is the cGMPs are defined,  
<sup>24</sup> for API drug manufacturers in Q7 -- ICH

<sup>1</sup> At all times that ZHP  
<sup>2</sup> developed and manufactured valsartan, ZHP  
<sup>3</sup> was required to comply with both the  
<sup>4</sup> outside standards for cGMP that applied  
<sup>5</sup> to its manufacture and development of  
<sup>6</sup> valsartan, as well as the internal  
<sup>7</sup> protocols that had been implemented by  
<sup>8</sup> ZHP, pursuant to those outside sources;  
<sup>9</sup> would you agree with that statement?

<sup>10</sup> A. Can you --

<sup>11</sup> MS. DAVIDSON: Objection.

<sup>12</sup> THE WITNESS: Can you tell  
<sup>13</sup> me which outside standards,  
<sup>14</sup> please?

<sup>15</sup> BY MR. SLATER:

<sup>16</sup> Q. For example, ICH Q7.

<sup>17</sup> A. If you look at ICH Q7, on  
<sup>18</sup> the first page of the text of the  
<sup>19</sup> document, as well as every other  
<sup>20</sup> guidance, FDA makes a statement that this  
<sup>21</sup> guidance is not binding and that it is a  
<sup>22</sup> recommendation and it's the current  
<sup>23</sup> thinking of FDA regarding a topic.

<sup>24</sup> Q. Please define for me which

<p style="text-align: right;">Page 34</p> <p>1 cGMP standards applied to ZHP in the      2 development and manufacture of valsartan.      3 Please list for me those sources of      4 objective authority, whether internal or      5 external to ZHP, which applied to them      6 and to which they had to comply.</p> <p>7 MS. DAVIDSON: That was two      8 questions.</p> <p>9 MR. SLATER: Great.</p> <p>10 BY MR. SLATER:</p> <p>11 Q. Please answer.</p> <p>12 MS. DAVIDSON: Which one,      13 the first or second?</p> <p>14 MR. SLATER: I'm not going      15 to -- I'm not going to banter with      16 you.</p> <p>17 BY MR. SLATER:</p> <p>18 Q. Please answer the question.</p> <p>19 MS. DAVIDSON: I'm going to      20 object. That was a compound      21 question.</p> <p>22 I think that the rules of a      23 deposition are you ask one      24 question at a time, and there were</p>	<p style="text-align: right;">Page 36</p> <p>1 BY MR. SLATER:</p> <p>2 Q. Please answer the question.</p> <p>3 A. I have here in front of me      4 ICH Q7. Q7 is a guidance issued by      5 FDA -- ICH and adopted by FDA. It's      6 title is, Good Manufacturing Practice      7 Guidance for Active Pharmaceutical      8 Ingredients, Guidance for Industry,      9 September 2016.</p> <p>10 On the very Page Number 1,      11 which is after Page Number 4, 4 as in IV,      12 it states, Good manufacturing practice      13 guidance for active pharmaceutical      14 ingredients. Guidance for industry.</p> <p>15 And there is a black box      16 which says, This guidance represents the      17 current thinking of the Food and Drug      18 Administration on this topic. It does      19 not establish any rights for any person      20 and is not binding on FDA or the public.      21 You can use an alternative approach if it      22 satisfies the requirements of the      23 applicable statutes and regulations.</p> <p>24 So --</p>
<p>1 two in there.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. Please answer the question.</p> <p>4 A. Can you ask the question      5 again, please?</p> <p>6 Q. Please list for me each      7 source of -- rephrase.</p> <p>8 Please list for me each      9 standard that applied to ZHP's      10 development and manufacture of valsartan      11 with regard to cGMP.</p> <p>12 I want to know what --      13 the universe of what you believe applied      14 to them that they had to adhere to is.</p> <p>15 MS. DAVIDSON: I'm going to      16 object again. I think it      17 actually, Adam, I think it's      18 important for this deposition to      19 understand, when you say ZHP, do      20 you also mean its subs or are you      21 specifically referring to ZHP?</p> <p>22 MR. SLATER: I don't even      23 understand your question. I'm not      24 going to go back-and-forth.</p>	<p style="text-align: right;">Page 35</p> <p>1 Q. Is that your complete answer      2 to my question?</p> <p>3 A. You're asking me for --      4 again, you know, this goes back to the      5 very first question, one of the previous      6 questions, of you saying specify the      7 standards.</p> <p>8 My point is, the GMPs are a      9 set of what-to-dos and not how-to-dos.      10 Industry needs to follow the how-to-dos      11 and those how-to-dos are based on -- for      12 API manufacturers, are based on Q7, which      13 ZHP followed and did.</p> <p>14 Q. I'd like you to list for      15 me -- rephrase.</p> <p>16 Please list for me those      17 cGMP standards, whether they are external      18 to ZHP or internal to ZHP, such as      19 standard operating procedures that      20 applied to ZHP in its development and      21 manufacture of valsartan.</p> <p>22 I need to know the list of      23 what you believe they were required to      24 comply with when they developed and</p>

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1 manufactured the valsartan.  
 2 Please answer the question.  
 3 MS. DAVIDSON: Objection.  
 4 Compound. Asked and answered.  
 5 Vague.  
 6 BY MR. SLATER:  
 7 Q. I'm not asking you to read  
 8 the standards to me. I'm asking for you  
 9 to list them for me, please.  
 10 A. So -- so if I'm going to  
 11 list them, Mr. Slater, I would go to  
 12 ICH Q7, okay; and I would go to the table  
 13 of contents.  
 14 Would you like me to list  
 15 them for you?  
 16 Q. I don't need you to list for  
 17 me the table of contents.  
 18 If you think that ICH Q7 was  
 19 something that ZHP needed to comply with,  
 20 per my question, you can say ICH Q7.  
 21 I don't need you to read me  
 22 the table of contents.  
 23 A. The sections -- sorry.  
 24 MS. DAVIDSON: Dr. Afnan,

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1 you've got to leave me time to  
 2 object.  
 3 Because I object to that. I  
 4 don't even think it was a  
 5 question.  
 6 THE WITNESS: The current  
 7 standard in industry, and as  
 8 practiced by the regulators, is to  
 9 have a quality system which is  
 10 effectively defined through a  
 11 guidance of FDA, which talks about  
 12 quality systems.  
 13 And it's defined -- or it's  
 14 stipulated as what it needs to  
 15 have in Q7. It requires,  
 16 effectively, the Quality 7, the  
 17 training of the personnel, the  
 18 buildings and facilities, the  
 19 process equipment, documentation  
 20 and records, material management,  
 21 production and in-process  
 22 controls, packaging and  
 23 identification labeling for APIs  
 24 and intermediates, validating the

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1 lab controls, validation, change  
 2 control, rejection of materials,  
 3 complaints and recalls.

4 Now, about the internal  
 5 standards, that would be the list  
 6 of ZHP's SOPs, which I do not  
 7 have. That was beyond the scope  
 8 of my agreement.

9 BY MR. SLATER:

10 Q. When you say "beyond the  
 11 scope" of your agreement, what do you  
 12 mean?

13 A. Not agreement, my agreement.  
 14 It was -- I was not tasked with assessing  
 15 all the GMPs of ZHP.

16 Q. Got it.

17 MR. SLATER: We can take  
 18 down the deposition notice. Let's  
 19 put up as Exhibit --

20 BY MR. SLATER:

21 Q. Well, let me ask you,  
 22 Doctor, do you have your report in front  
 23 of you?

24 A. I do.

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1 MR. SLATER: We have a  
 2 December 23, 2022, report. For  
 3 the record, we'll put it up on the  
 4 screen just so everybody can see  
 5 it. And it will be for the court  
 6 reporter to have it. But that  
 7 will be Exhibit-2.

8 - - -  
 9 (Whereupon, Exhibit Afnan-2,  
 10 No Bates, 12/23/22 Expert Report  
 11 of Ali Afnan, Ph.D., was marked  
 12 for identification.)

13 - - -  
 14 BY MR. SLATER:

15 Q. Doctor, subject to an e-mail  
 16 that we got that had some corrections of  
 17 a few things within the report, is this  
 18 the only report -- well, rephrase. Let  
 19 me ask it differently.

20 Is this the only report  
 21 you've written in this case?

22 A. I -- the amended report was,  
 23 I think, submitted on January 11, 2023.

24 Q. Sorry. I had a malfunction

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1 here. 2 Let me ask the question 3 again. 4 The December 23, 2022, 5 report we have on the screen is the first 6 report you wrote in this case, correct? 7 A. Yes. 8 Q. Did that contain all the 9 opinions you had formed at the time that 10 you authored that report? 11 MS. DAVIDSON: Objection. 12 THE WITNESS: Did it 13 contain -- can you -- can you 14 rephrase the question, please? 15 BY MR. SLATER: 16 Q. On the screen we have your 17 December 23, 2022, report. 18 A. Yes. 19 Q. Did that report contain the 20 opinions you had formed at the time that 21 you signed that report on December 23, 22 2022? 23 A. Yes. 24 MR. SLATER: Let's take that	1 Q. Let me ask the question 2 differently. 3 Why did you serve an amended 4 report on January 11, 2023? 5 A. I discovered typographical 6 errors in it. And then also I came 7 across a version of M7 which I had not 8 referred to in my December 23 report, it 9 was the earlier version of M7. 10 Q. In your work outside of this 11 case, did you ever apply M7 in any case, 12 any situation? 13 A. In my work I have -- during 14 the development phase of working with 15 some clients, I do look -- I have looked 16 at M7. 17 Q. What was the context? 18 MS. DAVIDSON: Adam, before 19 you go on. 20 Dr. Afnan, as Adam has 21 cautioned his witnesses, I know 22 that some of your consulting work 23 may be confidential. And you're 24 not obligated to violate

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1 down and put up as Exhibit-3 the 2 amended report now. 3 - - - 4 (Whereupon, Exhibit Afnan-3, 5 No Bates, 1/11/23 Expert Report of 6 Ali Afnan, Ph.D., was marked for 7 identification.) 8 - - - 9 BY MR. SLATER: 10 Q. Exhibit-3 is the January 11, 11 2023, report. 12 Is that the second report 13 you wrote in this case? 14 A. Yes. 15 Q. Can you tell me what, if 16 anything, is different between the 17 January 11 report and the December 23, 18 2022, report? 19 I don't need you to find 20 page numbers. If you can just tell me 21 generally what you did with the report 22 between those two dates. 23 MS. DAVIDSON: Objection. 24 BY MR. SLATER:	1 confidentiality of relationships 2 or agreements with clients in 3 order to respond to this 4 deposition. 5 So please keep that in mind 6 when you're asked any questions 7 about your consulting work. 8 Thank you. 9 THE WITNESS: Thank you. 10 As I said, it was during 11 drug development processes. 12 BY MR. SLATER: 13 Q. Was that API drug 14 development process or finished dose drug 15 development process? 16 A. In both cases, it was a new 17 drug, so it was both development of the 18 API and also, then, development of the 19 drug product. 20 Q. When did that occur? 21 A. Over the last five years. I 22 don't have the exact dates. 23 Q. Let's go back to Exhibit-2. 24 Attached to Exhibit-2 is

<p style="text-align: right;">Page 46</p> <p>1 your C.V., curriculum vitae, correct?</p> <p>2 A. Yes.</p> <p>3 Q. You're currently the</p> <p>4 president and founder of Step Change</p> <p>5 Pharma, Inc.</p> <p>6 What is that company?</p> <p>7 A. It's a consulting company.</p> <p>8 Q. What do you consult on?</p> <p>9 A. Various projects all related</p> <p>10 to pharma; from drug development, which</p> <p>11 is a much lesser extent of my work, to</p> <p>12 GMP remediation, manufacturing</p> <p>13 enhancements.</p> <p>14 Q. When you say drug</p> <p>15 development is a lesser part of your</p> <p>16 work, what do you mean by that?</p> <p>17 A. I have -- I have, maybe, two</p> <p>18 or three clients who work in that area.</p> <p>19 Q. What does GMP remediation</p> <p>20 mean?</p> <p>21 A. Firms who have gotten into</p> <p>22 trouble with FDA or the European Agency</p> <p>23 or any of the others and need to</p> <p>24 effectively remediate.</p>	<p style="text-align: right;">Page 48</p> <p>1 MR. SLATER: I'll ask it</p> <p>2 again.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. Do pharmaceutical</p> <p>5 manufacturers hope to receive warning</p> <p>6 letters from the FDA?</p> <p>7 MS. DAVIDSON: Objection.</p> <p>8 THE WITNESS: Pharma</p> <p>9 manufacturers are in the business</p> <p>10 of making a drug or drugs and</p> <p>11 selling them, not receiving</p> <p>12 warning letters.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. That's -- I didn't ask you</p> <p>15 what business they're in. I asked you a</p> <p>16 simple question.</p> <p>17 Is the answer yes or no?</p> <p>18 MS. DAVIDSON: Objection.</p> <p>19 Maybe rephrase the question.</p> <p>20 MR. SLATER: I don't think I</p> <p>21 need to.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. Can you answer, please?</p> <p>24 MS. DAVIDSON: Well, I'm</p>
<p style="text-align: right;">Page 47</p> <p>1 Q. Did ZHP need to do GMP</p> <p>2 remediation?</p> <p>3 A. They got 483 obligations,</p> <p>4 which they addressed. That's what I call</p> <p>5 remediation.</p> <p>6 Q. Have any of your clients</p> <p>7 received FDA warning letters for which</p> <p>8 you had to perform GMP remediation?</p> <p>9 MS. DAVIDSON: Objection.</p> <p>10 BY MR. SLATER:</p> <p>11 Q. You can answer, Doctor.</p> <p>12 A. Yes.</p> <p>13 Q. How many times?</p> <p>14 A. I don't recall. Truthfully,</p> <p>15 I don't recall.</p> <p>16 Q. Is it a good thing for a</p> <p>17 pharmaceutical manufacturer to receive a</p> <p>18 warning letter from the FDA? Does the</p> <p>19 manufacturer like getting warning</p> <p>20 letters? Is that something they like to</p> <p>21 get?</p> <p>22 MS. DAVIDSON: Objection.</p> <p>23 That was three questions. Vague.</p> <p>24 I think that's all.</p>	<p style="text-align: right;">Page 49</p> <p>1 objecting again.</p> <p>2 THE WITNESS: The answer is</p> <p>3 no, because that's why they engage</p> <p>4 third parties to do the work to</p> <p>5 help them.</p> <p>6 BY MR. SLATER:</p> <p>7 Q. What do you mean by that,</p> <p>8 that's why they retain third parties to</p> <p>9 do the work to help them?</p> <p>10 I don't understand. What's</p> <p>11 that mean?</p> <p>12 A. They -- at times, firms work</p> <p>13 with external parties like me, a GMP</p> <p>14 remediation company, to assist them with</p> <p>15 putting -- you know, correcting whatever</p> <p>16 has been identified, partly -- yeah.</p> <p>17 Q. ZHP received a warning</p> <p>18 letter in November 2018, correct?</p> <p>19 A. Yes.</p> <p>20 Q. That letter -- rephrase.</p> <p>21 That warning letter</p> <p>22 identified violations of cGMPs, correct?</p> <p>23 MS. DAVIDSON: Objection.</p> <p>24 BY MR. SLATER:</p>

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1 Q. Can you answer the question,  
 2 please?

3 MS. DAVIDSON: I believe the  
 4 witness was thinking. And I do  
 5 want to state for the record --

6 MR. SLATER: I think the  
 7 problem is, Jessica, when you're  
 8 objecting, he doesn't know if he's  
 9 allowed to answer the question.

10 MS. DAVIDSON: No, I  
 11 explained at the beginning of the  
 12 deposition --

13 MR. SLATER: I don't want to  
 14 argue with you. I'm not going to  
 15 engage with you.

16 MS. DAVIDSON: Okay. I  
 17 don't want to engage with you  
 18 either, Adam.

19 But I want to point out that  
 20 you had many witnesses last week  
 21 who took up to five minutes to  
 22 answering questions. We did not  
 23 badger them or interrupt the  
 24 deposition to address that. Many

1 obviously that document needs to  
 2 be in front of him. I don't think  
 3 Dr. Afnan memorized the warning  
 4 letter or maybe he did.

5 MR. SLATER: Do you want to  
 6 testify for him that he didn't  
 7 memorize the warning letter or do  
 8 you want to try to let him to  
 9 answer the question?

10 MS. DAVIDSON: I don't know,  
 11 maybe he did memorize it. My  
 12 point is, if you're asking --

13 MR. SLATER: Why are you  
 14 trying to block him from answering  
 15 the question?

16 MS. DAVIDSON: I am not  
 17 trying to block him from answering  
 18 the question, Adam. As somebody  
 19 who repeatedly told his witness  
 20 last week to look at a document, I  
 21 think this is kind of an ironic  
 22 accusation.

23 If you want Dr. Afnan to  
 24 testify as to whether you read a

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1 of your witnesses took significant  
 2 periods of time.

3 If Dr. Afnan is thinking, I  
 4 don't think badgering him to  
 5 answer more quickly is fair or  
 6 appropriate deposition practice.

7 MR. SLATER: I disagree with  
 8 everything you just said and I'm  
 9 going to wait for the answer.

10 THE WITNESS: So a statement  
 11 on the warning letter is actually  
 12 boilerplate language which is on  
 13 every warning letter which FDA  
 14 issues.

15 BY MR. SLATER:

16 Q. The warning letter states,  
 17 in part, This warning letter summarizes  
 18 significant deviations from current good  
 19 manufacturing practice, cGMP, for active  
 20 pharmaceutical ingredients, API.

21 The letter says that, right?

22 MS. DAVIDSON: Objection.  
 23 If you're asking him to confirm  
 24 the reading of a document,

1 document accurately, obviously he  
 2 needs the document in front of  
 3 him.

4 BY MR. SLATER:

5 Q. Doctor, can you answer the  
 6 question, please?

7 A. I would appreciate,  
 8 actually, if you could put it up.

9 Q. Okay. You said that the  
 10 letter contained boilerplate language  
 11 that's found in all warning letters.

12 Do you remember you said  
 13 that a few moments ago?

14 A. Yes.

15 Q. What's the boilerplate  
 16 language you were referring to?

17 A. If you put it up, I'll show  
 18 you.

19 Q. Let's put it up.

20 MR. SLATER: This will be  
 21 exhibit, what, 3? 4, okay.  
 22 Exhibit-4 will be the warning  
 23 letter.

24 - - -

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1 (Whereupon, Exhibit Afnan-4,  
 2 PRINSTON00077339-7344, 11/29/18  
 3 Letter, Godwin to Du, was marked  
 4 for identification.)  
 5 - - -

6 THE WITNESS: If you would  
 7 be kind enough to scroll down,  
 8 please.

9 So the boilerplate language  
 10 is, This warning letter summarizes  
 11 significant deviations from  
 12 current good manufacturing  
 13 practice, cGMP 4.

14 And then the rest of it  
 15 would be for whether it's testing,  
 16 whether it's APIs, or whether it's  
 17 for drug product.

18 The next paragraph is also  
 19 boilerplate language.

20 BY MR. SLATER:

21 Q. Does every manufacturer of  
 22 pharmaceutical products receive a warning  
 23 letter that contains the boilerplate  
 24 language you just described every year?

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1 Every warning letter that is  
 2 issued has those two paragraphs in  
 3 it.

4 BY MR. SLATER:

5 Q. The warning letter sent by  
 6 the FDA to ZHP, dated November 29, 2018,  
 7 identified what they described in their  
 8 letter as significant deviations from  
 9 current good manufacturing practice for  
 10 active pharmaceutical ingredients.

11 That's what the letter says,  
 12 correct?

13 A. That's what the letter says,  
 14 yes.

15 Q. The warning letter also  
 16 states, Because your methods, facilities  
 17 or controls for manufacturing,  
 18 processing, packing or holding do not  
 19 conform to cGMP, your API are adulterated  
 20 within the meaning of Section  
 21 501(a)(2)(B) of the Federal Food, Drug  
 22 and Cosmetic Act, correct?

23 That's what it says in the  
 24 letter, correct?

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1 A. So if you can read the  
 2 question back to me, because that was an  
 3 interesting question.

4 Q. Well, I'll ask it -- I'll  
 5 ask it differently. Well, actually, I'll  
 6 ask it again.

7 Does every pharmaceutical  
 8 manufacturer, under the jurisdiction of  
 9 the FDA, receive a warning letter every  
 10 year with regard to all products that  
 11 they manufacture that contains the two  
 12 boilerplate sections you just pointed out  
 13 to me?

14 MS. DAVIDSON: Objection.

15 THE WITNESS: If a firm is  
 16 inspected, and it's very rare that  
 17 FDA inspects every year, if a firm  
 18 is inspected and observations are  
 19 given to it, the firm responds.

20 FDA will then make a  
 21 determination, based on the  
 22 observations, the response and the  
 23 EIR whether to issue a warning  
 24 letter or not.

1 A. That's what it says in the  
 2 letter.

3 MR. SLATER: You can take  
 4 the letter down.

5 BY MR. SLATER:

6 Q. When you were at the FDA,  
 7 did you have any responsibility to  
 8 oversee API manufacturing of drugs?

9 MS. DAVIDSON: Objection.

10 THE WITNESS: In my years at  
 11 FDA, and the way FDA currently  
 12 works, there is no individual  
 13 person responsible for API  
 14 manufacturing. It's effectively  
 15 managed through either the review  
 16 division or through ORA for  
 17 inspection, but primarily through  
 18 the review division.

19 And, no, I was not solely  
 20 individually responsible for API  
 21 manufacturing.

22 BY MR. SLATER:

23 Q. When you were at the FDA,  
 24 did you have any responsibility in

<p>Page 58</p> <p>1 connection with any matters focused on 2 API manufacturing of pharmaceutical drugs 3 at any time?</p> <p>4 MS. DAVIDSON: Objection.</p> <p>5 BY MR. SLATER:</p> <p>6 Q. Let me ask the question 7 differently. I just want to make it 8 cleaner.</p> <p>9 A. Yes.</p> <p>10 Q. At the FDA -- I'm going to 11 ask it differently.</p> <p>12 At the FDA, did you have 13 responsibility in any way, or involvement 14 in any way, with any matter involving the 15 manufacture of API?</p> <p>16 A. So was I involved with the 17 review of API applications or 18 documentation? The answer is yes.</p> <p>19 But your question is vague 20 in saying I was responsible solely for 21 manufacture of API.</p> <p>22 Q. I never asked if you were 23 solely responsible. So the vague point 24 that you're concerned about, I never</p>	<p>Page 60</p> <p>1 conversation with someone? 2 Can you explain to me what 3 that involvement would have been?</p> <p>4 A. The review --</p> <p>5 MS. DAVIDSON: Whoa. You 6 got to give me a minute to object. 7 That was, like, seven 8 questions. So I'm not sure -- it 9 was super compound. 10 If you know which one to 11 answer, go ahead.</p> <p>12 THE WITNESS: Which one was 13 I involved with? The review 14 process and approval process of 15 APIs in FDA is very -- complex is 16 the wrong word. 17 It's a team effort. So 18 there are multiple divisions, 19 multiple groups, who actually get 20 engaged in the review process. 21 The review process consists 22 of, for APIs, depending whether 23 it's a generic or whether it's a 24 brand, whether it's existing or</p>
<p>Page 59</p> <p>1 actually asked that.</p> <p>2 A. My apologies.</p> <p>3 Q. You don't have to apologize.</p> <p>4 What I'm asking, in a broad 5 sense, is, what, if any, involvement you 6 ever had with any matter involving API 7 manufacture when you were at the FDA?</p> <p>8 MS. DAVIDSON: Objection.</p> <p>9 THE WITNESS: I believe I've 10 answered that.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. Just to be clear, would you 13 please tell me what involvement you ever 14 had with any matter involving API 15 manufacturing?</p> <p>16 A. I have been involved with 17 the review of API manufacturing 18 processes.</p> <p>19 Q. In what context would you 20 have reviewed the processes? Would it 21 have been where you went out and did an 22 inspection? Would it have been review of 23 an application? Would you have reviewed 24 a document? Would you have had a</p>	<p>Page 61</p> <p>1 whether it's new, it will 2 effectively be reviewed by 3 different multidisciplinary 4 groups. 5 And where I have been 6 involved was to look at the 7 manufacturing processes in 8 relation to APIs. 9 It is then reviewed. The 10 agency, the FDA, asks for an 11 inspection of the facility, if it 12 doesn't have enough information 13 about the GMP status of the 14 facility. And then it makes a 15 collective decision. 16 BY MR. SLATER: 17 Q. I didn't ask you what the 18 FDA does to oversee API. I asked what 19 involvement, if any, you've ever had when 20 you were at the FDA with any matter 21 involving API, what you did. 22 A. I answered that. 23 Q. I need you to tell me what 24 you did.</p>

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<p>1 MS. DAVIDSON: Objection. 2 THE WITNESS: I answered 3 that. I said I was involved with 4 the review of the application to 5 FDA.</p> <p>6 BY MR. SLATER:</p> <p>7 Q. When you say "review of the 8 application to FDA," what specific 9 application is that? Is there a name for 10 that application?</p> <p>11 A. That comes as part of either 12 ANDA, NDA or DMF.</p> <p>13 Q. And in your role, what would 14 your responsibility have been in looking 15 at those applications? What were you 16 looking for? What were you doing?</p> <p>17 A. My role was to look at, 18 effectively, the manufacturing process, 19 the controls, what FDA calls chemistry 20 manufacturing and controls of the 21 processes.</p> <p>22 Q. What were you looking for 23 when you were looking at that material?</p> <p>24 A. Whether the process was</p>	<p>1 to determine genotoxicity of a 2 chemical compound.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. When you worked at 5 AstraZeneca, were you involved in the 6 development or manufacture of API?</p> <p>7 A. Yes.</p> <p>8 Q. What was your responsibility 9 in that context?</p> <p>10 A. Process control.</p> <p>11 Q. What does that mean, process 12 control?</p> <p>13 A. Controlling the 14 manufacturing process to end up with the 15 result that was determined as desirable.</p> <p>16 Q. When you say to end up with 17 the result that was desired, what does 18 that mean?</p> <p>19 A. So that the API had the 20 right yield, the right specifications, 21 environmental conditions were met, 22 process went as planned.</p> <p>23 Q. Was it a cGMP requirement 24 that the process control would result in</p>
<p>1 feasible or not, whether the critical 2 process parameters which have been 3 identified correlated to the critical 4 quality attributes and how those 5 attributes were controlled, and whether 6 they met USD requirements or if those 7 were in-house specifications.</p> <p>8 Q. Do you hold yourself out as 9 an expert in organic chemistry?</p> <p>10 A. No, not as an expert in 11 organic chemistry. No.</p> <p>12 Q. Are you holding yourself out 13 as an expert in FDA regulation of API and 14 finished drug products?</p> <p>15 A. I have extensively worked in 16 the API and drug product domain.</p> <p>17 Q. Do you hold yourself out as 18 an expert with regard to the 19 identification of genotoxic impurities in 20 drug substances?</p> <p>21 MS. DAVIDSON: Objection.</p> <p>22 THE WITNESS: That's 23 actually two questions. And I am 24 not a toxicologist, so I'm not one</p>	<p>1 an output of product as you just 2 described it?</p> <p>3 A. Was it a cGMP requirement -- 4 so I was involved in API manufacturing 5 for new products.</p> <p>6 What is the GMP requirement? 7 Once it's approved, your controls need to 8 provide consistent quality, consistent -- 9 you know, consistently meet 10 specifications; so the definition here is 11 based on meeting specifications.</p> <p>12 Q. Is that required by GMP, the 13 manufacture of a drug product, whether 14 API or finished dose, that meets the 15 specifications?</p> <p>16 A. So --</p> <p>17 MS. DAVIDSON: Objection. 18 Please, Dr. Afnan, 30 19 seconds is all I ask.</p> <p>20 THE WITNESS: Okay. Sorry. 21 Can you ask the question 22 again, please?</p> <p>23 BY MR. SLATER:</p> <p>24 Q. Sure.</p>
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<p>1        You indicated that the      2 process control was intended to ensure      3 the output of drug product with      4 consistent quality, consistently meeting      5 the specifications.</p> <p>6        I'm asking if that was      7 required by cGMP?</p> <p>8        A. The question requires a very      9 detailed answer; and the very detailed      10 answer you're going to object to.</p> <p>11      Okay. You say that is, it a      12 GMP requirement? So, effectively, if you      13 develop a product and you say, for      14 example, its yield is between 80 percent      15 to 85 percent, one of the requirements      16 are that you have a -- develop a trend of      17 meeting that.</p> <p>18      Now, once you develop, you      19 know, one batch produced at 90 percent      20 and another batch produced at 70 percent,      21 that's not a deviation from the GMPs.      22 You need to look at it. But that's not a      23 deviation from the GMPs.</p> <p>24      That's why I'm struggling</p>	<p>1        THE WITNESS: I think I've      2 answered that. But, again, I'll      3 try.</p> <p>4        cGMPs allow you to fail in      5 manufacturing a batch. So it's      6 not a case of, you know, the cGMPs      7 require that if I make 1,000      8 batches, they all need to be      9 identical.</p> <p>10      cGMPs do allow batch      11 failures. If a batch fails, that      12 means it doesn't meet its      13 specifications. cGMPs allow that.</p> <p>14 BY MR. SLATER:</p> <p>15      Q. Would I be correct that cGMP      16 allows for the possibility of a batch      17 failure, as you just described it, as      18 long as you detect and identify the batch      19 failure?</p> <p>20      MS. DAVIDSON: Objection.</p> <p>21      THE WITNESS: That's a      22 circular question. If a batch      23 fails and it is rejected, then,      24 obviously, it doesn't reject</p>
<p>1 with the question.</p> <p>2      Q. One of the things you said      3 that your process control was supposed to      4 ensure was consistent quality.</p> <p>5      Is the output of API with      6 consistent quality a requirement of cGMP?</p> <p>7      A. So, again, you know,      8 consistent quality, it depends how -- how      9 the specs are -- specifications for the      10 API are determined.</p> <p>11     So if the specifications,      12 which are approved by if regulator, you      13 know, should you meet those      14 specifications with every batch? And the      15 answer is, that's the ideal goal. Will      16 you meet those every single time? And      17 the answer is, no, you will not.</p> <p>18     So, again, it's not a      19 black-or-white response that I can give      20 you.</p> <p>21     Q. Does cGMP require that a      22 manufacturing process yield API that      23 meets the specifications for that API?</p> <p>24     MS. DAVIDSON: Objection.</p>	<p>1 itself. It is assessed, analyzed      2 and, therefore, the quality unit      3 rejects it.</p> <p>4      So if the quality unit      5 reject it, then -- that's what I      6 meant by your question is      7 circular.</p> <p>8 BY MR. SLATER:</p> <p>9      Q. So if I understand      10 correctly, cGMP allows a batch failure,      11 but that's only if the batch failure is      12 identified by the quality unit and then      13 that batch failure is identified and that      14 batch is rejected? Do I understand that      15 correctly?</p> <p>16      MS. DAVIDSON: Objection.      17 Mischaracterizes his testimony.</p> <p>18      THE WITNESS: Yes, it does      19 mischaracterize my testimony.      20 That's not what I said.</p> <p>21 BY MR. SLATER:</p> <p>22      Q. All right. So let me ask      23 you a different question, then.      24 Is it your testimony that</p>
<p>1</p>	<p>1</p>

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<p>1 with the question.</p> <p>2      Q. One of the things you said      3 that your process control was supposed to      4 ensure was consistent quality.</p> <p>5      Is the output of API with      6 consistent quality a requirement of cGMP?</p> <p>7      A. So, again, you know,      8 consistent quality, it depends how -- how      9 the specs are -- specifications for the      10 API are determined.</p> <p>11     So if the specifications,      12 which are approved by if regulator, you      13 know, should you meet those      14 specifications with every batch? And the      15 answer is, that's the ideal goal. Will      16 you meet those every single time? And      17 the answer is, no, you will not.</p> <p>18     So, again, it's not a      19 black-or-white response that I can give      20 you.</p> <p>21     Q. Does cGMP require that a      22 manufacturing process yield API that      23 meets the specifications for that API?</p> <p>24     MS. DAVIDSON: Objection.</p>	<p>1</p>
<p>1</p>	<p>1</p>

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<sup>1</sup> cGMP does not require that the API  
<sup>2</sup> manufactured with a drug process --  
<sup>3</sup> rephrase.

<sup>4</sup> Are you telling me that cGMP  
<sup>5</sup> does not require that the API  
<sup>6</sup> manufacturing process result in the  
<sup>7</sup> output of API that meets the approved  
<sup>8</sup> specifications for the drug?

<sup>9</sup> MS. DAVIDSON: Objection.  
<sup>10</sup> Again, mischaracterizes testimony.

<sup>11</sup> MR. SLATER: I'm asking the  
<sup>12</sup> question.

<sup>13</sup> MS. DAVIDSON: You said, are  
<sup>14</sup> you saying, so I thought you were  
<sup>15</sup> characterizing his prior  
<sup>16</sup> testimony. If not, great.

<sup>17</sup> THE WITNESS: Your approach  
<sup>18</sup> to cGMPs is that the cGMPs  
<sup>19</sup> determine -- define every activity  
<sup>20</sup> of every day. Again, I go back to  
<sup>21</sup> very early on when I was saying,  
<sup>22</sup> you know, the GMPs define what to  
<sup>23</sup> be done and not how to be done.

<sup>24</sup> So the cGMPs do not specify

<sup>1</sup> sure I actually understand your  
<sup>2</sup> question clearly.

<sup>3</sup> BY MR. SLATER:

<sup>4</sup> Q. Do you want me to explain  
<sup>5</sup> it?

<sup>6</sup> A. Please.

<sup>7</sup> Q. If you don't understand it  
<sup>8</sup> clearly, then I don't want you to answer  
<sup>9</sup> a question you don't understand clearly.

<sup>10</sup> A. Thank you.

<sup>11</sup> Q. Do you know what  
<sup>12</sup> specifications for API means? In  
<sup>13</sup> general, do you understand what that  
<sup>14</sup> means?

<sup>15</sup> MS. DAVIDSON: Objection.

<sup>16</sup> THE WITNESS: You have a  
<sup>17</sup> definition for that, right?

<sup>18</sup> BY MR. SLATER:

<sup>19</sup> Q. I'm asking you, you're the  
<sup>20</sup> expert. So tell me, what's the  
<sup>21</sup> definition of what the specifications for  
<sup>22</sup> API is?

<sup>23</sup> What are specifications?

<sup>24</sup> Why do they exist?

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<sup>1</sup> that, you know what, the batch  
<sup>2</sup> needs to be rejected or approved.  
<sup>3</sup> The cGMPs create a system, and  
<sup>4</sup> that's the uniqueness of the U.S.  
<sup>5</sup> regulations, creates a system  
<sup>6</sup> within which a manufacturer  
<sup>7</sup> manufactures, tests and comes to a  
<sup>8</sup> disposition decision.

<sup>9</sup> So cGMPs is a system within  
<sup>10</sup> a system. It's like saying, here  
<sup>11</sup> is a system for operating within  
<sup>12</sup> pharma, and then I have -- I have  
<sup>13</sup> a bad batch or I have a semi-bad  
<sup>14</sup> batch. Again, not every result  
<sup>15</sup> of -- related to specifications of  
<sup>16</sup> a batch, you know, can result in a  
<sup>17</sup> rejection.

<sup>18</sup> BY MR. SLATER:

<sup>19</sup> Q. What is the purpose of  
<sup>20</sup> having specifications for a manufactured  
<sup>21</sup> API?

<sup>22</sup> MS. DAVIDSON: Objection.  
<sup>23</sup> Vague.

<sup>24</sup> THE WITNESS: If -- I am not

<sup>1</sup> A. They are --

<sup>2</sup> MS. DAVIDSON: Objection.  
<sup>3</sup> Ali, I don't want to yell at  
<sup>4</sup> you. You got to give me time to  
<sup>5</sup> object.

<sup>6</sup> THE WITNESS: You know,  
<sup>7</sup> specifications are effectively  
<sup>8</sup> the -- the bandwidth that we  
<sup>9</sup> operate in, okay. That's what the  
<sup>10</sup> specification is, it specifies a  
<sup>11</sup> parameter and says, this  
<sup>12</sup> parameter, plus or minus a  
<sup>13</sup> variance, needs to be met or  
<sup>14</sup> should be met.

<sup>15</sup> There are specifications and  
<sup>16</sup> there are limits. So limits  
<sup>17</sup> are -- in the regulated  
<sup>18</sup> pharmaceutical world are internal  
<sup>19</sup> to the firm. Specifications is  
<sup>20</sup> what you agree with the regulator.

<sup>21</sup> BY MR. SLATER:

<sup>22</sup> Q. What is the purpose of  
<sup>23</sup> establishing specifications for a  
<sup>24</sup> manufactured API?

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1 A. What's the purpose of  
 2 specifications for a manufactured API?  
 3 It's so that when we talk about that API,  
 4 we are talking about the same product,  
 5 regardless of who the manufacturer is.

6 However, there are  
 7 differences between those manufactured  
 8 products by different manufacturers.

9 MS. DAVIDSON: We've been  
 10 going about an hour. Is this a  
 11 good time for a break?

12 MR. SLATER: I'm actually  
 13 ready to keep going for as long as  
 14 we possibly can. I don't need a  
 15 break.

16 MS. DAVIDSON: Dr. Afnan, do  
 17 you need a break?

18 THE WITNESS: I would  
 19 appreciate a break.

20 MS. DAVIDSON: Okay. Let's  
 21 take ten minutes.

22 VIDEO TECHNICIAN: We're off  
 23 the record at 10:37 a.m.

24 - - -

1 range," what do you mean?

2 A. So, for example, it will say  
 3 98 percent to 102 percent purity. It  
 4 says, you know, impurities or a specific  
 5 impurity below a certain limit. It  
 6 states unknown impurities below .1  
 7 percent or 1 percent or .5 percent. It  
 8 varies from product to product.

9 Q. If there are unknown  
 10 impurities -- well, rephrase.

11 Are all -- rephrase.

12 Are all unknown impurities  
 13 evaluated in the same way in terms of  
 14 whether or not it's acceptable for them  
 15 to exist in an API?

16 MS. DAVIDSON: Objection.

17 THE WITNESS: If it's an  
 18 unknown impurity, how would one  
 19 assess it to see if it's supposed  
 20 to be there or not? So could you  
 21 please rephrase your question?

22 BY MR. SLATER:

23 Q. No. Actually, I think I'll  
 24 ask a follow-up question.

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1 (Whereupon, a brief recess  
 2 was taken.)

3 - - -

4 VIDEO TECHNICIAN: We're  
 5 back on the record at 10:47 a.m.

6 BY MR. SLATER:

7 Q. You said the purpose of  
 8 specifications for an API is so that when  
 9 we talk about the API it's the same  
 10 product, regardless of manufacturer,  
 11 correct?

12 MS. DAVIDSON: Objection.

13 THE WITNESS: Okay. "Same"  
 14 is an interesting word to use.  
 15 And if I used same, it was -- it  
 16 has to be qualified.

17 So, effectively, when we  
 18 look at USP monographs, it defines  
 19 specifications for an API. And  
 20 that has a range for purity,  
 21 impurity, unknown impurity, so on  
 22 and so forth.

23 BY MR. SLATER:

24 Q. When you say there's "a

1 Unknown impurities need to  
 2 be assessed in order to identify what  
 3 they are because all impurities are not  
 4 treated the same, in terms of how much  
 5 can exist in an API or drug product,  
 6 correct?

7 MS. DAVIDSON: Objection.

8 THE WITNESS: ICH Q3A  
 9 specifically defines and allows  
 10 for unknown impurities to remain  
 11 in a product. And an unknown  
 12 impurity is that, it's not known;  
 13 we don't know what it does.

14 You -- you know, all that is there  
 15 is what level and what the limit  
 16 is for it.

17 BY MR. SLATER:

18 Q. If an unknown impurity is  
 19 below whatever threshold you are applying  
 20 as a manufacturer and the amount of that  
 21 impurity under that threshold is  
 22 sufficient to kill every single person  
 23 who takes the drug product, is that  
 24 acceptable?

<p>1 MS. DAVIDSON: Objection.      2 THE WITNESS: If it's an      3 unknown impurity, how would a      4 manufacturer know of the effect of      5 an unknown impurity?      6 BY MR. SLATER:      7 Q. In forming your opinions in      8 this case, is it your foundational      9 assumption that it's impossible for an      10 API manufacturer to identify the unknown      11 impurities created by a manufacturing      12 process?      13 MS. DAVIDSON: Objection.      14 BY MR. SLATER:      15 Q. Let me ask the question      16 differently.      17 A. Okay.      18 Q. Is it your testimony that it      19 is impossible for an API manufacturer,      20 like ZHP, to identify the source of      21 impurities that are below the applicable      22 threshold but are not known?      23 Are you saying it's      24 impossible to figure out what they</p>	<p>Page 78      1 A. Wow.      2 MS. DAVIDSON: I don't know      3 if that "wow" covers my objection.      4 You didn't give me a chance.      5 But I was intending to      6 object.      7 THE WITNESS: Well, that was      8 an objection from me.      9 MS. DAVIDSON: I don't think      10 you're allowed to do that,      11 Dr. Afnan.      12 THE WITNESS: Sorry.      13 MS. DAVIDSON: That's my      14 job.      15 THE WITNESS: Can you repeat      16 your question, please? Or I would      17 really prefer you to rephrase the      18 question.      19 MR. SLATER: Please read the      20 question back to him, please.      21 - - -      22 (Whereupon, the court      23 reporter read the following part      24 of the record:</p>
<p>Page 79      1 actually are?      2 MS. DAVIDSON: Objection.      3 THE WITNESS: I didn't say      4 it's impossible. We need to go      5 back to ICH and see what ICH says,      6 even though it's a guidance and it      7 allows for unknown impurities      8 below a certain limit to be      9 present.      10 There is no requirement to      11 go and identify every single      12 unknown impurity and see      13 whether -- you know, what the      14 function of that impurity is.      15 BY MR. SLATER:      16 Q. So that comes back to my      17 prior question.      18 If there's no requirement to      19 identify all unknown impurities, would it      20 be acceptable, under cGMP, if there was      21 an unknown impurity below the ICH Q3A      22 threshold that, if ingested by a human      23 being, would kill the person within one      24 day?</p>	<p>Page 81      1 "Question: So that comes      2 back to my prior question.      3 "If there's no requirement      4 to identify all unknown      5 impurities, would it be      6 acceptable, under cGMP, if there      7 was an unknown impurity below the      8 ICH Q3A threshold that, if      9 ingested by a human being, would      10 kill the person within one day?"      11 - - -      12 MS. DAVIDSON: Objection.      13 THE WITNESS: I don't even      14 know how to begin to answer that      15 question, because it is such a      16 far-fetched question that -- you      17 know, if it was below the      18 threshold limit?      19 If it's below the threshold      20 limit, the pharma manufacturer      21 doesn't know about it, because      22 it's unknown.      23 So the GMPs allow -- or,      24 more specifically, the</p>

<p>1       specifications allow to have 2       unknown impurities. 3       Now, if it's a generic API, 4       then it's following the branded 5       API. If it's a brand API, then it 6       will have gone through multiple 7       different clinical studies where 8       the intent would have been to 9       identify a poisonous compound.</p> <p>10 BY MR. SLATER:</p> <p>11 Q. Are all potential impurities 12 subject to the same threshold?</p> <p>13 A. So the threshold depends on 14 your analytical methodology. It's not 15 just the case of, you know, here I draw a 16 line and I call it a threshold and then 17 move on.</p> <p>18 So I think your -- your 19 question needs exploring, it needs to be 20 changed.</p> <p>21 Q. Did you ever hear of the 22 cohort of concern?</p> <p>23 A. Yes.</p> <p>24 Q. When did you first hear of</p>	<p>Page 82</p> <p>1       Q. What is the cohort of 2       concern? What substances comprise the 3       cohort of concern?</p> <p>4       MS. DAVIDSON: Objection.</p> <p>5 BY MR. SLATER:</p> <p>6       Q. Do you know?</p> <p>7       A. I would appreciate if you 8       could show me M7, and I will direct you 9       to it.</p> <p>10 Q. I don't have M7 at my 11 fingertips.</p> <p>12 A. I don't have the list 13 learned by heart either.</p> <p>14 Q. N-nitroso compounds are part 15 of the cohort of concern, correct?</p> <p>16 MS. DAVIDSON: Objection.</p> <p>17 THE WITNESS: Again, this is 18 not something I have learned by 19 heart. I would really appreciate 20 if we could look at M7.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. You don't know, as you sit 23 here right now without looking at M7, 24 whether N-nitroso compounds are part of</p>
<p>1 the cohort of concern?</p> <p>2 A. The cohorts of concern are 3 in M7, that's where I heard.</p> <p>4 Q. When? When did you first 5 learn of the cohort of concern?</p> <p>6 MS. DAVIDSON: Objection.</p> <p>7 THE WITNESS: As I have said 8 earlier, when I was working on -- 9 when I was working on drug 10 development with -- outside of 11 this project, this case, I had 12 read M7.</p> <p>13 So that goes back, you know, 14 before I started with this 15 project.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. What is the cohort of 18 concern?</p> <p>19 A. So M7 defines -- or lists 20 cohorts of concern, which effectively 21 lists a different set of types of 22 products or compounds and says, these are 23 of concern.</p> <p>24 There is a, you know --</p>	<p>Page 83</p> <p>1 the cohort of concern?</p> <p>2 MS. DAVIDSON: Objection.</p> <p>3 Badgering the witness.</p> <p>4 THE WITNESS: I am --</p> <p>5 MS. DAVIDSON: Please don't 6 interrupt me, Dr. Afnan.</p> <p>7 If you would like to pull up 8 M7, that is permissible in this 9 deposition, as Adam told his own 10 witnesses.</p> <p>11 THE WITNESS: Okay.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. Is the answer you can't 14 answer the question without seeing M7?</p> <p>15 MS. DAVIDSON: Objection.</p> <p>16 Mischaracterizes his testimony.</p> <p>17 Badgering the witness.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. I need to know, Doctor.</p> <p>20 Are you telling me that 21 without looking at M7 you can't tell me 22 if N-nitroso compounds are part of the 23 cohort of concern?</p> <p>24 MS. DAVIDSON: Same</p>

<p>1       objections.</p> <p>2       THE WITNESS: So my response</p> <p>3       is delayed or not given to you.</p> <p>4       The reason I'm asking for M7</p> <p>5       is because you're using a very</p> <p>6       specific phrase, "N-nitroso</p> <p>7       compounds." I would like to see</p> <p>8       if M7 says N-nitroso compounds.</p> <p>9       BY MR. SLATER:</p> <p>10      Q. Do you -- do you know what</p> <p>11     NDMA is?</p> <p>12      A. Yes.</p> <p>13      Q. What is NDMA?</p> <p>14      A. Nitrosodimethylamine.</p> <p>15      Q. Do you know -- do you know</p> <p>16     what NDEA is?</p> <p>17      MS. DAVIDSON: I'm sorry.</p> <p>18      Objection. When you say what it</p> <p>19     is, are you asking him what the</p> <p>20     abbreviation stands for or what it</p> <p>21     is? I think the question is</p> <p>22     vague.</p> <p>23       BY MR. SLATER:</p> <p>24       Q. Do you know what NDEA is?</p>	<p>Page 86</p> <p>1       MS. DAVIDSON: Otherwise I'm</p> <p>2       going to object as vague.</p> <p>3       MR. SLATER: Okay.</p> <p>4       BY MR. SLATER:</p> <p>5       Q. During the time that ZHP</p> <p>6       developed and manufactured valsartan API,</p> <p>7       did the threshold approach to impurities</p> <p>8       apply to NDMA and NDEA?</p> <p>9       A. Your question is based on</p> <p>10      today, looking back at 2000 -- you know,</p> <p>11      prior to 2018.</p> <p>12      So to actually look at</p> <p>13     cohorts of concern, M7, I think, based on</p> <p>14     my recollection, is that an assessment</p> <p>15     needs to be done of the process to see</p> <p>16     whether nitroso compounds would be</p> <p>17     formed. And if there is no -- if the</p> <p>18     conclusion is that no mutagenic compounds</p> <p>19     are formed, then the unknown impurities</p> <p>20     will remain unknown.</p> <p>21      ICH Q3A is also on the side</p> <p>22     of -- you know, parallel to M7, not on</p> <p>23     the side, parallel to M7. And ICH Q3A,</p> <p>24     at that time, and even today, says</p>
<p>Page 87</p> <p>1       MS. DAVIDSON: So I'm going</p> <p>2       to have to have the same objection</p> <p>3       if you don't want to clarify the</p> <p>4       question.</p> <p>5       THE WITNESS: It stands for</p> <p>6       nitrosodiethylamine.</p> <p>7       BY MR. SLATER:</p> <p>8       Q. Are NDMA and NDEA N-nitroso</p> <p>9       compounds?</p> <p>10      A. Yes.</p> <p>11      Q. Does the threshold approach</p> <p>12     to impurities apply to NDMA and NDEA?</p> <p>13      MS. DAVIDSON: Objection.</p> <p>14      Are you asking -- can you repeat</p> <p>15      the question, madam court</p> <p>16      reporter?</p> <p>17       BY MR. SLATER:</p> <p>18      Q. Sure.</p> <p>19      Does the threshold approach</p> <p>20     to impurities apply to NDMA and NDEA?</p> <p>21      MS. DAVIDSON: So you're</p> <p>22      asking currently? Is that a</p> <p>23      present-tense question?</p> <p>24      Q. During the time --</p>	<p>Page 89</p> <p>1       certain impurities can be below the</p> <p>2       threshold limit, and below .1 percent you</p> <p>3       can have unknown -- undefined,</p> <p>4       uncharacterized impurities.</p> <p>5       Q. One of the things ZHP was</p> <p>6       required to do was to assess its</p> <p>7       manufacturing process for valsartan API,</p> <p>8       correct?</p> <p>9       A. It was, yes. And it did.</p> <p>10      Q. Why did you add the part</p> <p>11     about "and it did"?</p> <p>12      A. Because -- because it did.</p> <p>13      Q. But did I ask you if they</p> <p>14     did or not?</p> <p>15      A. No.</p> <p>16      MS. DAVIDSON: Objection. I</p> <p>17      don't know if that's actually a</p> <p>18      question you're asking in a</p> <p>19      deposition. That's -- you're</p> <p>20      obviously badgering the witness.</p> <p>21      MR. SLATER: I don't think I</p> <p>22      am. What I'm doing is trying</p> <p>23      to -- I'm trying to determine the</p> <p>24      witness's understanding of my</p>

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1      questions. And I'm trying to 2      understand why it is he said they 3      did, when I didn't ask the 4      question. 5      So I'm trying to understand 6      why he said it when I didn't ask 7      the question about whether they 8      did it or not. 9      MS. DAVIDSON: Okay. I 10     don't think you're really trying 11     to understand that. This is 12     Dr. Afnan's first deposition, as 13     he indicated at the beginning of 14     the deposition. 15     So I think let's just give 16     the man a break and move on with 17     actual questioning. 18     MR. SLATER: Right. We're 19     here to give ZHP and their expert 20     witness on GMP a break today. 21     MS. DAVIDSON: I don't know 22     what that means. 23 BY MR. SLATER: 24 Q. ZHP was required to		1 back to me, please? 2      Q. I'll ask it again. I'll try 3 to be even clearer. 4      A. Sure. 5      Q. In terms of assessing the 6 risks of introduction of a chemical or a 7 substance to the manufacturing process, 8 one of the risks that needed to be 9 assessed was whether that chemical or 10 substance would introduce impurities into 11 the process, correct? 12      A. Yes. 13      Q. And that assessment is 14 expected to be or required by cGMP to be 15 a scientific assessment, correct? 16      A. Can you tell me what you 17 mean by "scientific"? 18      Q. The assessment needs -- 19 rephrase. 20      The assessment needed to be 21 based on scientific information that was 22 available to those people who were in 23 charge of this process, for example, 24 information that was available in the
	Page 91	Page 93
1      assess -- rephrase. 2      When ZHP changed the 3 manufacturing process for valsartan, did 4 they need to understand the properties of 5 the chemicals and substances that they 6 were introducing to the process? 7      MS. DAVIDSON: Objection. 8      Vague. 9      THE WITNESS: Can you please 10 let me know what you mean by 11 "properties" of substances? 12 BY MR. SLATER: 13 Q. Their function, their 14 benefits to the process, potentially, and 15 their potential risks as being introduced 16 into the process as well. 17      Did they need to assess 18 those things? 19      A. Yes. 20      Q. One of the things that that 21 assessment needed to involve was the 22 potential risk of introduction of 23 impurities into the product, correct? 24      A. Can you read that question	1 scientific literature, correct? 2      A. So the way they would be 3 expected and the way which is current 4 practice, and was practice at that time, 5 was for the firm to look at the process, 6 to look at the raw materials that it was 7 buying, making sure that those materials 8 met specifications; and then look at the 9 process and assess whether an undesired 10 side reaction will take place. 11      If those did not take place, 12 then there would not be a logical reason 13 for -- a scientific reason for going and 14 trolling through the scientific community 15 to see what else would happen. 16      So it is a -- it isn't a 17 black-and-white, you know what, they 18 should have -- they should have looked at 19 everything in the scientific community, 20 because that's not logical. 21      Q. Before ZHP introduced a new 22 substance into the manufacturing process, 23 it needed to understand -- well, let me 24 walk back, actually.	

<p>1 One of the things you said      2 is that they must look at the raw      3 materials it was buying and make sure      4 they meet the specifications; is that one      5 of the things you said?      6 A. They -- industry generally      7 requires to qualify its vendors.      8 Q. What does it mean to qualify      9 a vendor?      10 A. To look at a vendor, to make      11 sure that the vendor has acceptable GMPs,      12 and the substance which is coming in,      13 there are specifications, and those      14 specifications can be met.      15 Q. In terms of understanding      16 the specifications for the substances      17 that are being purchased from vendors,      18 that would include, for example, if a      19 solvent was being purchased for use in a      20 manufacturing process, correct?      21 A. Sorry, can you repeat the      22 question?      23 Q. Sure.      24 When you talk about looking</p>	<p>Page 94</p> <p>1 API product, are you?      2 MS. DAVIDSON: Objection.      3 BY MR. SLATER:      4 Q. Is that what you mean, that      5 staying in the process means it ends      6 up -- that that solvent is a part of the      7 finished API that comes out of the      8 process?      9 MR. SLATER: I just want to      10 understand what the doctor is      11 saying.      12 MS. DAVIDSON: Objection.      13 You asked a question and I      14 objected. And then you asked a      15 new question, and now I don't know      16 which of the two questions is      17 pending.      18 If you changed your first      19 question to the second question, I      20 object to the second question.      21 BY MR. SLATER:      22 Q. When you refer to the      23 process -- rephrase.      24 When you refer to the</p>
<p>1 at the specifications for the substances      2 that are being purchased from vendors,      3 that would include, for example, if the      4 manufacturer purchased a solvent to be      5 used in the manufacturing process,      6 correct?      7 A. So there is a qualification      8 to my response, which is defined in      9 ICH Q7. ICH Q7 categorizes intermediates      10 and raw materials which are purchased for      11 use in an API process.      12 And that effectively depends      13 whether that solvent is expected to      14 remain in the process or whether it will      15 be removed from the process during      16 processing.      17 So as you get closer to that      18 solvent remaining in the process, they --      19 the regulatory requirement or the GMP      20 requirement goes up.      21 Q. When you say if that solvent      22 remains in the process, you're not saying      23 it has to remain so long that it ends up      24 in the finished drug -- in the finished</p>	<p>Page 95</p> <p>1 substance, in this case we're talking      2 about a solvent, remaining in the      3 process, are you saying remaining in the      4 process until the end so that the solvent      5 is actually in the API product that is      6 yielded by the process?      7 MS. DAVIDSON: Objection.      8 THE WITNESS: So the way the      9 regulations work, the way the GMPs      10 work, if you get a solvent which      11 is used in your processing, the      12 question that comes up that needs      13 to be taken into consideration by      14 the firm is whether the downstream      15 processing steps would effectively      16 remove that solvent from the      17 process.      18 However, in industrial      19 setting productions, it is      20 extremely rare for all the      21 solvents to be removed from the      22 process. And for that reason,      23 most of the solvents which are      24 used in industry all have an</p>

<p>1       allowable limit in the API, in the 2       finished API.</p> <p>3 BY MR. SLATER:</p> <p>4       Q. Does ICH Q7 require that 5 when ZHP purchased, for example, DMF from 6 a supplier, that it would either test the 7 DMF to see what it contained or rely on 8 the supplier's certificate of analysis 9 for that DMF to know what the DMF 10 contained?</p> <p>11       MS. DAVIDSON: Objection. 12       THE WITNESS: So Q7 doesn't 13 address ZHP at all. Q7 addresses 14 the what-to-do of pharma for APIs. 15       Again, if I look at Q7, Q7 16 would require the quality unit -- 17 a part of Q7 would require that 18 the solvent supplier be qualified, 19 that the solvent supplier sell, 20 your example of DMF, 21 dimethylformamide, and that 22 dimethylformamide would have a 23 specification which is provided by 24 the firm. And the C of A is</p>	<p>Page 98</p> <p>1       zinc chloride process? 2            MS. DAVIDSON: Objection. 3            THE WITNESS: According to 4 FDA inspections of ZHP and, in 5 particular, the 2018 for-cause 6 inspection where the inspector 7 says there is a quality unit which 8 is well established, I would 9 conclude, based on that, that ZHP 10 would have been testing materials 11 coming in and would have had met 12 the regulatory requirements. 13       Because during the for-cause 14 inspection, the investigator says 15 their quality and it is 16 established it is operating well. 17 Previous inspections also found 18 that the quality unit was 19 functioning properly.</p> <p>20 BY MR. SLATER: 21       Q. So that I understand -- let 22 me just take a step back. 23       The reason I'm asking some 24 of these questions, so you know where I'm</p>
<p>1 provided with every batch. 2 According to current practice, or 3 good manufacturing practice, the 4 customer -- you know, a customer, 5 a manufacturer, an API 6 manufacturer, would qualify that 7 solvent, number one, and then it 8 would do IE testing of the batches 9 throughout the year. And at least 10 one batch would be fully tested, 11 as per the C of A. So if there 12 are five tests on the C of A, 13 those five tests would be run by 14 the API manufacturers.</p> <p>15 BY MR. SLATER: 16       Q. When you say they test per 17 the C of A, is that to compare what their 18 tests show versus what the certificate of 19 analysis shows should be within the 20 substance?</p> <p>21       A. Yes.</p> <p>22       Q. Do you know whether ZHP ever 23 looked at the certificate of analysis for 24 the DMF that it purchased and used in the</p>	<p>Page 99</p> <p>1 going is, you're coming in as an expert 2 to try to give opinions. You didn't live 3 through this, so you have to have your 4 own understanding of the facts, based on 5 the materials provided to you. 6       You looked at a lot of 7 documents, you looked at testimony, you 8 looked at various things in order to 9 understand what you think the facts are, 10 right?</p> <p>11       MS. DAVIDSON: Objection. I 12 don't know if that was actually a 13 question or -- 14       MR. SLATER: I'll ask 15 another question, because I don't 16 want to dismay you.</p> <p>17 BY MR. SLATER: 18       Q. Doctor, did you draw certain 19 factual assumptions in order to then form 20 opinions?</p> <p>21       MS. DAVIDSON: Objection. 22       THE WITNESS: Can you 23 rephrase or repeat the question?</p> <p>24 BY MR. SLATER:</p>

<p>1 Q. Sure.</p> <p>2 In order to form the</p> <p>3 opinions you formed in this case, did you</p> <p>4 rely on certain factual assumptions so</p> <p>5 that you said to yourself, okay, the</p> <p>6 facts are this, so based on these facts,</p> <p>7 my opinion is this?</p> <p>8 MS. DAVIDSON: Objection.</p> <p>9 BY MR. SLATER:</p> <p>10 Q. Did you do that as part of</p> <p>11 your methodology here?</p> <p>12 MS. DAVIDSON: Objection. I think when you ask one question,</p> <p>13 let's stop at that question, have</p> <p>14 the objection, have an answer.</p> <p>15 Because we have this pattern</p> <p>16 where I object and then you have,</p> <p>17 like, a follow-up question. I</p> <p>18 think it's creating a very unclear</p> <p>19 record.</p> <p>20 THE WITNESS: So the scope</p> <p>21 of my work was to assess whether</p> <p>22 they followed the GMPs</p> <p>23 specifically in relation to the</p>	<p>Page 102</p> <p>1 for the DMF it purchased for use in the</p> <p>2 zinc chloride process; do I understand</p> <p>3 you correctly?</p> <p>4 A. So, first of all, it's a</p> <p>5 solvent that is added to the process and</p> <p>6 then removed from the process, based on</p> <p>7 the process description that ZHP gives.</p> <p>8 That makes it a low-risk,</p> <p>9 low-category ingredient going into the</p> <p>10 process, number one.</p> <p>11 Number two, did I draw any</p> <p>12 conclusions that they must have looked at</p> <p>13 the C of A? And the answer is, if they</p> <p>14 did not, if they had not released their</p> <p>15 DMF, their solvents, they would have been</p> <p>16 cited over and over and over.</p> <p>17 Q. Is it your understanding, in</p> <p>18 forming your opinions, that ZHP looked at</p> <p>19 the certificates of analysis for the DMF</p> <p>20 it purchased for use in the zinc chloride</p> <p>21 process; yes or no?</p> <p>22 MS. DAVIDSON: Objection.</p> <p>23 THE WITNESS: ZHP looked at</p> <p>24 the C of As of the DMF it</p>	<p>Page 104</p>
<p>1 issues here and specifically in</p> <p>2 relation to plaintiffs' expert</p> <p>3 reports, which have been</p> <p>4 submitted.</p> <p>5 None of the expert</p> <p>6 reports -- the plaintiffs' expert</p> <p>7 reports, question the C of A or</p> <p>8 the solvent purchased by DMF.</p> <p>9 So did I have certain</p> <p>10 assumptions? My point is, I am a</p> <p>11 GMP assessor in this case, and I'm</p> <p>12 looking to see whether ZHP adhered</p> <p>13 to the GMPs or not.</p> <p>14 And in the same way an</p> <p>15 inspector would go on site and</p> <p>16 make conclusions and draw</p> <p>17 conclusions, I am relying on what</p> <p>18 I call facts that the inspector</p> <p>19 writes in her EIR and in her</p> <p>20 observations.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. So one of the assumptions</p> <p>23 that you drew in this case is that ZHP</p> <p>24 looked at the certificates of analysis</p>	<p>Page 103</p> <p>1 purchased.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. Did you ever look at any</p> <p>4 certificate of analysis in connection</p> <p>5 with the DMF that was purchased by ZHP</p> <p>6 and used in the zinc chloride process?</p> <p>7 I just want to know if you</p> <p>8 ever saw any certificate of analysis for</p> <p>9 that DMF.</p> <p>10 COURT REPORTER: Ms.</p> <p>11 Davidson, you're on mute.</p> <p>12 MS. DAVIDSON: Sorry about</p> <p>13 that. I was objecting.</p> <p>14 I'm glad you can read lips.</p> <p>15 THE WITNESS: So ZHP, in its</p> <p>16 investigation that it sent to FDA,</p> <p>17 lists the DMF suppliers and the</p> <p>18 quality of those DMF supplies.</p> <p>19 Now, did I look at the</p> <p>20 specific C of A? I honestly do</p> <p>21 not recall.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. That's all I asked you.</p> <p>24 I just asked you if you saw</p>	<p>Page 105</p>

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1 any certificate of analysis for the DMF.	1 of the documents that was of
2 MS. DAVIDSON: Objection. I	2 significance to me.
3 don't know if that's a question	3 BY MR. SLATER:
4 or --	4 Q. Let's go to Page 7 of 236 of
5 BY MR. SLATER:	5 this document, please. I'm looking at
6 Q. So the point is, you don't	6 the bottom part of the page.
7 recall, correct?	7 This states, Based on the
8 MS. DAVIDSON: Objection.	8 investigation and the evaluation of the
9 Asked and answered.	9 current valsartan route of
10 THE WITNESS: I looked at	10 synthesis (zinc chloride process), this
11 the data that was presented to	11 impurity is most likely formed during the
12 FDA, which FDA accepted. That, I	12 azide quenching by nitric acid of the API
13 do remember.	13 manufacturing process.
14 I do not remember	14 Do you see where I'm reading
15 specifically looking at the C of A	15 under Figure 3.1, which says, The
16 of DMF.	16 structure of NDMA? Do you see where I'm
17 MR. SLATER: We're going to	17 reading?
18 put up an exhibit. For purposes	18 A. Yes.
19 of this deposition, I think this	19 Q. Continuing, it says,
20 is Exhibit 5 or 6. This is	20 Specifically, dimethylformamide (DMF) one
21 Exhibit-5.	21 of the solvents used in Step 4 (Crude)
22 - - -	22 stage, may contain trace amount of
23 (Whereupon, Exhibit Afnan-5,	23 dimethylamine as an impurity.
24 PRINSTON00075810-6099, Deviation	24 Furthermore, during the tetrazole

Page 107	Page 109
1 Investigation Report, was marked	1 formation step, dimethylformamide may be
2 for identification.)	2 susceptible to low-level decomposition
3 - - -	3 under high temperature to produce trace
4 BY MR. SLATER:	4 amount of dimethylamine, either by thermo
5 Q. So to be clear, Exhibit-5 on	5 decomposition or hydrolysis.
6 the screen is the deviation investigation	6 Do you see where I just
7 report, which was actually marked at a	7 read?
8 prior deposition Peng Dong as ZHP 210.	8 A. Yes.
9 Do you see that document on	9 Q. Did you read that language
10 the screen?	10 as part of your evaluation of this case
11 A. I see it. I would	11 in forming your opinions?
12 appreciate it if it could also be put	12 A. Yes.
13 into the share folder.	13 Q. So when you formed your
14 Q. It's there.	14 opinions in this case, you were aware
15 A. Okay. Thank you.	15 that dimethylamine could be introduced --
16 Q. Have you seen this document	16 rephrase.
17 before?	17 So when you formed your
18 A. That is the investigation I	18 opinions in this case, you understood
19 was referring to.	19 that ZHP had determined that the DMF that
20 Q. Was this a document that was	20 it was using in the zinc chloride process
21 significant to you in evaluating this	21 may contain a trace amount of
22 case and forming your opinions?	22 dimethylamine as an impurity before it
23 MS. DAVIDSON: Objection.	23 even was added to the process; you had
24 THE WITNESS: This was one	24 read that language and understood it when

<p>1 you formed your opinions, correct?      2 MS. DAVIDSON: Objection.      3 THE WITNESS: So what is      4 interesting is, what is the date      5 of this document? Can you go to      6 the top or the bottom, or      7 wherever, and tell me what's the      8 date of that document?      9 MS. DAVIDSON: I believe,      10 Dr. Afnan, if it was placed in      11 the --      12 MR. SLATER: It's November      13 5, 2018.      14 BY MR. SLATER:      15 Q. Please answer the question.      16 MS. DAVIDSON: Adam, you      17 interrupted me.      18 Dr. Afnan, I believe if a      19 document has been placed in the      20 share drive, or whatever it's      21 called, as Adam noted, that you      22 can move up and down on it      23 yourself.      24 You can open it; is that</p>	<p>Page 110</p> <p>1 NDMA coming from.      2 BY MR. SLATER:      3 Q. My question was simply      4 whether you took that information that I      5 just read with you into consideration      6 when you formed your opinions.      7 It's a yes-or-no question.      8 I just want to know if you took it into      9 account when you formed your opinions.      10 MS. DAVIDSON: Objection.      11 Again, I'm going to have to object      12 every time you say it's a      13 yes-or-no question.      14 THE WITNESS: I actually do      15 not believe I can give you a      16 yes-or-no answer.      17 So if -- again, you know,      18 FDA said -- Dr. Gottlieb, on the      19 30th of August, 2018, says,      20 because it was not anticipated      21 that NDMA would occur at these      22 levels in the manufacture of the      23 valsartan API, manufacturers would      24 not have been testing for it.</p>
<p>1 correct?      2 THE WITNESS: Yes.      3 MS. DAVIDSON: I just wanted      4 to clarify that.      5 THE WITNESS: Thank you.      6 So this was an investigation      7 taking place -- in fact, this was      8 Version Number 2, as it says on      9 the screen.      10 This was an investigation      11 which was taking place where ZHP      12 was trying to find the root cause      13 and the method of formation of      14 NDMA in the process.      15 This is not a statement      16 about, you know what, this is what      17 we did. They are testing every      18 single possible pathway to      19 formation of NDMA. This document      20 is being written with a 20/20      21 hindsight that NDMA was present in      22 valsartan. And as requested and      23 required by their system and FDA,      24 they're digging into where is this</p>	<p>Page 111</p> <p>1 That's what FDA said.      2 BY MR. SLATER:      3 Q. Can you just answer my      4 question, please?      5 A. I did. I can't give you a      6 yes-or-no answer.      7 Would you like to rephrase      8 your question?      9 Q. You told me a moment ago      10 that you read this language when you were      11 preparing your report, correct?      12 A. Yes.      13 Q. So you knew this information      14 when you wrote your report, correct?      15 MS. DAVIDSON: Objection.      16 THE WITNESS: I had to take      17 everything that I read in the      18 context of why, when, how, and why      19 am I reading it.      20 Again, this is a 20/20      21 hindsight in 2018, back end of      22 2018, where ZHP is making --      23 effectively trying to make NDMA.      24 And this is the report of them</p>

<p>1 trying, trying, to make NDMA. So 2 they write this report when they 3 are trying to make NDMA. 4 So did I read this when I -- 5 before writing my report? Yes, 6 the answer is, I read this before 7 I wrote my report.</p> <p>8 BY MR. SLATER:</p> <p>9 Q. Having read this, did you 10 consider the possibility that 11 dimethylamine was introduced to the zinc 12 chloride process as an impurity of DMF?</p> <p>13 Did you consider that as one 14 of the pathways by which the NDMA got 15 into the process; yes or no?</p> <p>16 MS. DAVIDSON: Objection. I 17 think that's --</p> <p>18 THE WITNESS: Again, the 19 scope of my work was to look at 20 the plaintiff experts reports and 21 assess that, as well as the GMP 22 assessment. My scope was not to 23 dig into the chemistry of the 24 formation of NDMAs.</p>	<p>Page 114</p> <p>1 to me -- indicated, to me, that DMF, 2 which is a very common solvent, actually, 3 in the pharma industry, that if it's used 4 it would have followed certain -- certain 5 common practices, certain behaviors, you 6 know, certain practices that were 7 practiced across industry.</p> <p>8 And, again, your question of 9 could this have come with DMF, the answer 10 goes back to, this text that you're 11 showing me is -- is a hypothesis of this 12 could have come -- it's a hypothesis that 13 this could have come.</p> <p>14 As it says, it's most 15 likely formed during the azide quenching 16 by nitrous acid of the API. One of the 17 solvents used and inspected for may 18 contain trace amounts of dimethylamine as 19 an impurity.</p> <p>20 Q. You just said that because 21 DMF was a very common solvent you would 22 expect that there would be certain 23 familiarity with DMF within the industry 24 and that certain common practices would</p>
<p>1 And, again, I'll repeat, 2 this report is a look-back after 3 ZHP knew NDMA had been formed, and 4 they were now looking at the 5 pathways of formation of NDMA. 6 This is after -- this 7 report, this language, is after 8 the language by Scott Gottlieb, 9 FDA commissioner, which said it 10 was not anticipated that NDMA 11 would occur at these levels in the 12 manufacture of the valsartan APIs 13 and manufacturers were not testing 14 for it.</p> <p>15 BY MR. SLATER:</p> <p>16 Q. In forming your opinions, 17 did you consider the possibility that the 18 dimethylamine was introduced to the zinc 19 chloride process as an impurity of DMF as 20 the DMF was purchased?</p> <p>21 A. So there is no monograph for 22 DMF that I have been able to find. There 23 are specifications for levels of DMF in 24 finished APIs which effectively indicate,</p>	<p>Page 115</p> <p>1 be followed.</p> <p>2 Can you tell me, first of 3 all -- well, let me rephrase the 4 question.</p> <p>5 Do you have an opinion as to 6 what, as a matter of GMP, the people at 7 ZHP should have understood about the 8 potential impurities within DMF when they 9 decided to use that solvent in the zinc 10 chloride process?</p> <p>11 MS. DAVIDSON: Objection.</p> <p>12 THE WITNESS: Can you either 13 repeat or rephrase, please?</p> <p>14 BY MR. SLATER:</p> <p>15 Q. Sure. I'll rephrase it.</p> <p>16 I'm actually going to ask it differently.</p> <p>17 When you referred a moment 18 ago to certain practices in the industry, 19 what specific practices, with regard to 20 DMF, are you aware of that you would 21 expect ZHP followed?</p> <p>22 A. So industry --</p> <p>23 Q. I'm not asking -- by the 24 way, just to be clear, I'm not asking</p>

<p>Page 118</p> <p>1 generally. I'm asking with regard to 2 DMF.</p> <p>3 MS. DAVIDSON: Why don't you 4 just rephrase it, then? 5 Because --</p> <p>6 MR. SLATER: I don't think I 7 need to.</p> <p>8 MS. DAVIDSON: We need clear 9 questions.</p> <p>10 MR. SLATER: Thank you for 11 telling me my questions aren't 12 clear.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. Please answer, Doctor.</p> <p>15 MS. DAVIDSON: I'm sorry, 16 but you added a caveat after your 17 question. At this point, I don't 18 even know what the standing 19 question is.</p> <p>20 So I'm going to --</p> <p>21 MR. SLATER: That's good 22 because you're not the one who I'm 23 actually deposing. So we're good.</p> <p>24 MS. DAVIDSON: Adam, thank</p>	<p>Page 120</p> <p>1 would remain in the process. And ZHP 2 would have, at the beginning, when they 3 were developing the process and 4 follow-on, they would have used USP 5 standards for residual solvents.</p> <p>6 Q. When you say the spec would 7 be received, is that the certificate of 8 analysis?</p> <p>9 A. The specification without 10 being listed on the C of A, maybe. 11 Normally, the informations 12 are communicated separate from the 13 C of A. And a C of A would have been 14 submitted as part of the specifications.</p> <p>15 Q. You said something a few 16 moments ago about whether there was a 17 monograph for DMF.</p> <p>18 If there was a monograph for 19 DMF, would you expect that ZHP would have 20 looked at the monograph to get 21 information about the DMF?</p> <p>22 MS. DAVIDSON: Objection.</p> <p>23 THE WITNESS: I'm struggling 24 with ZHP getting information from</p>
<p>Page 119</p> <p>1 you. I object to your question as 2 vague and --</p> <p>3 MR. SLATER: I'll ask again, 4 because you're going to -- you're 5 going to have this conversation 6 with me, and it's not going to 7 really get us anywhere.</p> <p>8 So I'll ask it again, 9 Doctor.</p> <p>10 BY MR. SLATER:</p> <p>11 Q. What practices in the 12 industry would you expect that ZHP 13 followed with regard to the DMF that it 14 purchased and used in the zinc chloride 15 process?</p> <p>16 A. ZHP would have -- ZHP would 17 have effectively selected a supplier. 18 ZHP would have signed an agreement with 19 them. ZHP would have received a 20 specification from them. ZHP would have 21 then effectively developed the same 22 analytical methods or similar analytical 23 methods as them. ZHP would have 24 effectively looked for how this solvent</p>	<p>Page 121</p> <p>1 the monograph. 2 Could you please explain 3 your question -- that question to 4 me?</p> <p>5 BY MR. SLATER:</p> <p>6 Q. Sure.</p> <p>7 A. I apologize.</p> <p>8 Q. Sure.</p> <p>9 You said just a few moments 10 ago that you're not aware of a monograph 11 for DMF.</p> <p>12 Did I understand you 13 correctly when you said that a few 14 minutes ago?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. All right.</p> <p>17 MR. SLATER: We're going to 18 put up a new exhibit, which is 19 going to be Exhibit-6.</p> <p>20 - - -</p> <p>21 (Whereupon, Exhibit Afnan-6, 22 No Bates, Concise International 23 Chemical Assessment Document 31, 24 was marked for identification.)</p>

<p>1 - - -</p> <p>2 BY MR. SLATER:</p> <p>3 Q. This is a World Health Organization document from 2001.</p> <p>4 And as you can see, it's titled, N,N-dimethylformamide.</p> <p>5 Do you see that on the screen?</p> <p>6 A. Yes.</p> <p>7 Q. I assume you've not seen this before, based on the answer you gave me a couple of questions ago that you had not seen a monograph about DMF; is that correct?</p> <p>8 A. That's incorrect. I have seen this. That's not a monograph.</p> <p>9 Q. Okay. So let me -- let me start over.</p> <p>10 You've seen this document?</p> <p>11 A. Yes.</p> <p>12 Q. When did you see it?</p> <p>13 A. During the course of my reviews before writing my report.</p> <p>14 Q. Let's go to Page 5.</p>	<p>Page 122</p> <p>1 DMF, dated in 2001, the impurities of DMF sold commercially include dimethylamine?</p> <p>2 You would have seen that and known that when you wrote your report, correct?</p> <p>3 MS. DAVIDSON: Objection.</p> <p>4 That's not what he said.</p> <p>5 THE WITNESS: Can you rephrase, please, or repeat?</p> <p>6 BY MR. SLATER:</p> <p>7 Q. When you wrote your report --</p> <p>8 A. Yes.</p> <p>9 Q. -- you were aware that this publication stated that DMF sold commercially contains dimethylamine? You knew that when you wrote your report, right?</p> <p>10 MS. DAVIDSON: Objection.</p> <p>11 THE WITNESS: So here is my response, right. This is a general statement about DMF. The challenge is going to be multiple-fold.</p> <p>12 One is, was there a USP or</p>
<p>1 Looking at the bottom right corner, the first full paragraph under Section 2, titled, Identity and Physical/Chemical Properties.</p> <p>2 Do you see where I am on the bottom right?</p> <p>3 A. Yes.</p> <p>4 Q. The first paragraph under that heading, the last sentence says, DMF sold commercially contains trace amounts of methanol, water, formic acid and dimethylamine.</p> <p>5 And then there's a citation to a publication from 1994.</p> <p>6 Do you see that?</p> <p>7 A. Yes.</p> <p>8 Q. Did you see that when you wrote your report?</p> <p>9 A. As I said, I have seen the report, yes. I've seen this document.</p> <p>10 Yes.</p> <p>11 Q. So you knew when you wrote your report that according to a World Health Organization publication about</p>	<p>Page 123</p> <p>1 EP monograph for DMF? And the answer is still no.</p> <p>2 Did, effectively, every batch of product they manufactured have dimethylamine because of this statement? That's a conclusion that cannot be drawn.</p> <p>3 Even if it is there, again, if this is available to ZHP, then why would the FDA say that neither industry nor regulators knew about the formation of NDMA?</p> <p>4 BY MR. SLATER:</p> <p>5 Q. If ZHP had looked at scientific literature and read this document and seen that commercially sold DMF contains trace amounts of dimethylamine, they would have been on notice of the potential for dimethylamine to be introduced to the zinc chloride process as an impurity of the DMF they were purchasing; they would have been aware of that possibility, correct?</p> <p>6 MS. DAVIDSON: Objection.</p>

<p>1            THE WITNESS: ZHP considered      2 their process, looked at their      3 materials, looked at what they      4 were doing and assessed the      5 process for unknown impurities      6 which would cause problems,      7 unknown impurities which would be      8 mutagenic. And they came to the      9 conclusion, based on the      10 information they had, that that      11 was not the case.</p> <p>12          So saying because of this      13 document they should have known      14 about dimethylamine, I don't know      15 how that relates to assessment of      16 the -- risk assessment of the      17 manufacturing process. Because,      18 again, this is not a document that      19 one would go to if you are not      20 manufacturing for WHO regions.</p> <p>21          MS. DAVIDSON: Is this a      22 good time for a break?</p> <p>23          THE WITNESS: Yes.</p> <p>24          MR. SLATER: It's not,</p>	<p>Page 126</p> <p>1 something.      2 MS. DAVIDSON: Okay. Let's      3 go off the record.      4 MR. SLATER: You don't have      5 any water with you, Doctor?      6 THE WITNESS: I've run out.      7 MS. DAVIDSON: I'm sorry.      8 I'm sorry. No, we're not doing      9 this.</p> <p>10 MR. SLATER: You don't need      11 to be so angry. It's not      12 necessary to be so angry.      13 MS. DAVIDSON: I'm not      14 angry, Adam. I think you're the      15 one who is angry.      16 Let's take a seven-minute      17 break, and then we can do a few      18 minutes before your noon call.      19 Let's go off the record.      20 VIDEO TECHNICIAN: We're off      21 the record at 11:45 a.m.      22 - - -      23 (Whereupon, a brief recess      24 was taken.)</p>
<p>1            actually, because I have to do      2 something at noon, so I'd rather      3 go another ten minutes and then      4 take a break at noon. I have to      5 speak to somebody for about ten      6 minutes.</p> <p>7          MS. DAVIDSON: Noon is in 16      8 minutes, actually.</p> <p>9          MR. SLATER: I realize. I      10 don't need to stop exactly at      11 noon, but thank you for correcting      12 my time count.</p> <p>13          MS. DAVIDSON: Dr. Afnan,      14 would you like a break now or wait      15 until noon?</p> <p>16          THE WITNESS: I would --</p> <p>17          MR. SLATER: We can't go for      18 ten more minutes? I mean, come      19 on.</p> <p>20          MS. DAVIDSON: I'm asking      21 the witness.</p> <p>22          THE WITNESS: I would      23 appreciate it, because my mouth is      24 really dry and I need to drink</p>	<p>Page 127</p> <p>1            - - -      2 VIDEO TECHNICIAN: We're      3 back on the record at 11:54 a.m.      4 BY MR. SLATER:      5          Q. In evaluating this case --      6 actually, let me -- let me withdraw that.      7          MR. SLATER: Do you have      8 that document ready? Let's go to      9 the next exhibit, which is      10 Exhibit-7.      11 - - -      12 (Whereupon, Exhibit Afnan-7,      13 No Bates, Dimethylformamide:      14 Purification, Tests for Purity      15 and Physical Properties, was      16 marked for identification.)      17 - - -      18 BY MR. SLATER:      19          Q. On the screen is Exhibit-7,      20 a publication of the International Union      21 of Pure and Applied Chemistry, titled,      22 Dimethylformamide: Purification, Tests      23 for Purity and Physical Properties.      24 Do you see that?</p>

<p>1 A. Yes.</p> <p>2 Q. Have you ever seen this</p> <p>3 document?</p> <p>4 A. I do not recall. I don't</p> <p>5 think so, but I don't recall.</p> <p>6 Q. Let's go to Page 887,</p> <p>7 please, the middle of the page.</p> <p>8 You see in the middle of the</p> <p>9 page there's two formulas? Just below</p> <p>10 the first formula, do you see the word</p> <p>11 "formic acid"?</p> <p>12 A. Yes.</p> <p>13 Q. Looking at the middle of the</p> <p>14 page it says, Formic acid and</p> <p>15 dimethylamine are thus predominant</p> <p>16 impurities in DMF and determine the odor</p> <p>17 of the impure solvent.</p> <p>18 Do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. So this would be another</p> <p>21 publication, and just for the record,</p> <p>22 this publication is from 1977, stating</p> <p>23 that dimethylamine is a -- one of the</p> <p>24 predominant impurities in DMF.</p>	<p>Page 130</p> <p>1 process as an impurity of DMF?</p> <p>2 MS. DAVIDSON: Based on the</p> <p>3 two lines you read?</p> <p>4 MR. SLATER: I'm not going</p> <p>5 to go back-and-forth with you.</p> <p>6 BY MR. SLATER:</p> <p>7 Q. Please answer the question.</p> <p>8 A. So ZHP investigated the</p> <p>9 process with DMF and zinc chloride for</p> <p>10 two years, okay? This was reported to</p> <p>11 FDA, as well, after doing their research.</p> <p>12 So based on the work they</p> <p>13 did, based on the data, and based on the</p> <p>14 verification review by FDA, and their</p> <p>15 drug product manufacturing clients, the</p> <p>16 question of should they have known or</p> <p>17 not, the question of did they know about</p> <p>18 the formation of NDMA, and the answer is</p> <p>19 they did not know.</p> <p>20 FDA also states that they</p> <p>21 did not know. FDA says they do not know,</p> <p>22 nor did industry, knew where these were</p> <p>23 coming from.</p> <p>24 Q. As a matter of GMP, was ZHP</p>
<p>Page 131</p> <p>1 That's what this says,</p> <p>2 right?</p> <p>3 A. Those are the words on the</p> <p>4 screen.</p> <p>5 Q. Based on the literature I've</p> <p>6 shown you, would you agree with me that</p> <p>7 ZHP should have been aware that the DMF</p> <p>8 they were using in the zinc chloride</p> <p>9 process could contain dimethylamine as an</p> <p>10 impurity and could introduce the DMA to</p> <p>11 the process as an impurity of the DMF?</p> <p>12 Do you agree that ZHP should</p> <p>13 have been aware of that possibility?</p> <p>14 MS. DAVIDSON: I object.</p> <p>15 This is outside the scope of his</p> <p>16 opinions. He's not a chemist</p> <p>17 here.</p> <p>18 MR. SLATER: I'm not asking</p> <p>19 a chemistry question.</p> <p>20 BY MR. SLATER:</p> <p>21 Q. I'm asking, from a GMP</p> <p>22 perspective, should ZHP have been aware</p> <p>23 of the potential introduction of the</p> <p>24 dimethylamine to the zinc chloride</p>	<p>Page 133</p> <p>1 to understand -- rephrase.</p> <p>2 As a matter of current good</p> <p>3 manufacturing practices during the</p> <p>4 development and use of the zinc chloride</p> <p>5 process, was ZHP obligated, as a matter</p> <p>6 of cGMP, to be aware that one of the</p> <p>7 known impurities of commercially sold DMF</p> <p>8 was dimethylamine?</p> <p>9 Were they -- were they</p> <p>10 required to at least be aware of that</p> <p>11 fact in performing their risk assessment;</p> <p>12 yes or no?</p> <p>13 MS. DAVIDSON: Objection.</p> <p>14 Lacks foundation.</p> <p>15 THE WITNESS: ZHP would not</p> <p>16 be looking at the research based</p> <p>17 on publications. They would have</p> <p>18 been looking at the research based</p> <p>19 on what was happening in the</p> <p>20 chemistry, in their -- in the</p> <p>21 reactors, and the analytical</p> <p>22 results they were getting, and</p> <p>23 also based on the documentation</p> <p>24 they were receiving from their</p>

<p>1 suppliers. All of that was then 2 run by FDA.</p> <p>3 So to say that here is a 4 statement and because of this they 5 should have taken that into 6 consideration, I think it's a -- 7 it's an extrapolation of this to 8 something else that was not there. 9 ZHP looked at, effectively, 10 the process, they developed it. 11 They took two years. They ran 12 multiple samples. They did 13 extensive testing. Then they 14 decided to change the process, 15 which was then submitted to both 16 FDA as well as EDQM, the European 17 authority.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. I just want to be clear. 20 It's your opinion that ZHP, 21 as part of its risk assessment, did not 22 need to consult scientific literature at 23 all with regard to potential risks of the 24 substances they were using in their</p>	<p>Page 134</p> <p>1 at its chemical manufacturing process of 2 zinc chloride and DMF as a catalyst and a 3 solvent. ZHP took two years to develop 4 that process. ZHP extensively tested 5 that process and the products from that 6 process. ZHP used the methodology -- the 7 analytical methodology that was available 8 to it. Documented it all, then submitted 9 it to FDA. 10 ZHP even made an engineering 11 batch of -- of valsartan with the new 12 process, submitted all of that to FDA. 13 So with that body of 14 evidence versus going and looking 15 specifically in the universe of published 16 literature for dimethylamine is not 17 logical. So did they investigate? They 18 did investigate. 19 Q. And you agree with me, based 20 on the testimony you've read and the 21 stipulation you've read that was entered 22 in this case, ZHP did not do scientific 23 research in the literature with regard to 24 potential impurities or degradation of</p>
<p>Page 135</p> <p>1 manufacturing processes for valsartan? 2 MS. DAVIDSON: I'm going to 3 object that that mischaracterizes 4 his testimony. And it may be that 5 you're mischaracterizing his 6 testimony, because while he was 7 answering you were -- 8 MR. SLATER: I don't know 9 why you're giving a speech. You 10 objected, I -- 11 MS. DAVIDSON: -- engaged in 12 another conversation and not 13 looking at the camera and 14 listening to his answer. 15 And that may be why you 16 misheard it. 17 MR. SLATER: Counsel, please 18 don't make any more speaking 19 objections today. 20 BY MR. SLATER: 21 Q. Can you answer the question, 22 please? 23 A. So, again, to repeat my 24 answer -- to repeat my answer, ZHP looked</p>	<p>Page 137</p> <p>1 DMF, correct? 2 MS. DAVIDSON: Objection. 3 BY MR. SLATER: 4 Q. I understand you're saying 5 they didn't need to do it. 6 I'm just asking if you agree 7 they did not do it? 8 MS. DAVIDSON: Objection. 9 THE WITNESS: I didn't say 10 they didn't need to do it. You're 11 mischaracterizing what I said. 12 My statement, again, is that 13 they did do sufficient risk 14 assessments, sufficient assessment 15 of the process, the zinc chloride 16 process, before compiling the data 17 and submitting it to the 18 regulator. 19 MR. SLATER: Let's go off 20 the record. 21 VIDEO TECHNICIAN: We're off 22 the record at 12:04 p.m. 23 - - - 24 (Whereupon, a luncheon</p>

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1 recess was taken.)  
 2 - - -

3 VIDEO TECHNICIAN: We're  
 4 back on the record at 12:44 p.m.

5 BY MR. SLATER:

6 Q. You mentioned at one point  
 7 that you were retained to respond to the  
 8 plaintiff experts.

9 Do you remember you told me  
 10 that earlier?

11 A. They -- the scope of my  
 12 assignment was to effectively opine on  
 13 the subjects which are -- or the topics  
 14 which are raised against ZHP, yes.

15 Q. And did you understand your  
 16 role to be to, in essence, defend ZHP  
 17 against these accusations?

18 MS. DAVIDSON: I'm sorry, I  
 19 was on mute.

20 I'm objecting to that  
 21 question.

22 Court reporter, can you read  
 23 that question back?

24 - - -

1 for -- for correctness. And, at  
 2 the same time, look at the -- you  
 3 know, see what is being said and  
 4 whether there is -- whether that  
 5 is correct or not. Yeah.

6 BY MR. SLATER:

7 Q. Let's go back to the  
 8 document that we had up before. We're  
 9 back in Exhibit-7 now.

10 Looking at Page 887, where  
 11 it says, Formic acid and dimethylamine  
 12 are, thus, predominant impurities in DMF  
 13 and determine the odor of the impure  
 14 solvent.

15 My question is, do you  
 16 understand what that means when this  
 17 document and this publication says that  
 18 dimethylamine is a predominant impurity  
 19 in DMF? Do you understand what that  
 20 means?

21 MS. DAVIDSON: Objection.

22 THE WITNESS: How is  
 23 "predominant" qualified?

24 BY MR. SLATER:

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1 (Whereupon, the court  
 2 reporter read the following part  
 3 of the record:

4 "Question: And did you  
 5 understand your role to be to, in  
 6 essence, defend ZHP against these  
 7 accusations?"

8 - - -

9 MS. DAVIDSON: Yeah, that's  
 10 a very objectionable question. So  
 11 I'm doubling my objection.

12 MR. SLATER: I'll ask the  
 13 question differently.

14 BY MR. SLATER:

15 Q. Did you understand your role  
 16 to be to come up with arguments to defend  
 17 ZHP?

18 MS. DAVIDSON: Same  
 19 objections.

20 THE WITNESS: That was not  
 21 how I have approached this.

22 My approach to this is,  
 23 there are statements made by  
 24 plaintiff experts, assess them

1 Q. You see the words on the  
 2 page, I'm asking if you understand what  
 3 that means.

4 A. Okay. So I'm looking at the  
 5 word "predominant impurities," and I  
 6 would want to know what sort of a  
 7 percentage impurity that is.

8 Q. Why does that matter?

9 A. So there are no 100 percent  
 10 pure compounds in manufacturing grade  
 11 and, therefore, it is relevant because  
 12 it's a case of -- this is a -- this is a  
 13 scientific hypothetical statement, that  
 14 when you make this with this you have two  
 15 impurities or two of the degradation  
 16 products; the thermo degradation produces  
 17 this and this.

18 What is lacking in the  
 19 statement and, respectfully, in your  
 20 question, there is no information about  
 21 what the thermal conditions are, nor  
 22 about what the percentages or what the  
 23 levels of those two degradation products  
 24 are.

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1 Q. Was ZHP required to assess  
 2 the potential risks of potential  
 3 impurities that could be introduced to  
 4 the manufacturing process by the  
 5 substances that ZHP was using?  
 6 A. Can you repeat, please?  
 7 Q. Was ZHP supposed to assess  
 8 the potential risks from the potential  
 9 impurities that could be introduced to  
 10 the valsartan manufacturing process?  
 11 We're talking about the zinc  
 12 chloride process here. Let's talk about  
 13 that.  
 14 A. So ZHP, as per practice and  
 15 regulations, would have been looking and  
 16 would have needed to demonstrate looking  
 17 for potential impurity formations. And,  
 18 effectively, they would have needed to  
 19 validate it, which they did.  
 20 And then submit it to the  
 21 regulator, which they did. And the  
 22 regulator agreed with their assessment at  
 23 the time.  
 24 So what they were supposed

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1 first of all --  
 2 MR. SLATER: I don't need a  
 3 lecture. You can object to the  
 4 question. You have an objection  
 5 to form. He can answer.  
 6 You are not allowed to give  
 7 a speaking objection. Please  
 8 don't.  
 9 MS. DAVIDSON: Adam, you  
 10 have given speaking objections  
 11 endlessly in the last two weeks.  
 12 MR. SLATER: I'm asking you  
 13 to not to do another speaking  
 14 objection. Can you just please  
 15 let him answer the question?  
 16 MS. DAVIDSON: No. No.  
 17 Because, Adam --  
 18 MR. SLATER: So don't let  
 19 him answer. You're going to give  
 20 a speech. Go ahead. Give a  
 21 speech.  
 22 MS. DAVIDSON: Adam, you  
 23 interrupted Dr. Afnan. And as you  
 24 know, that is not appropriate

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1 to do they did do, and the regulator  
 2 agreed with that assessment.  
 3 Q. So you agree that ZHP was  
 4 required, as part of its assessment, to  
 5 assess the potential risks from the  
 6 potential impurities that could be  
 7 introduced to the zinc chloride process  
 8 from the substances that were being used;  
 9 you agree with that, correct?  
 10 MS. DAVIDSON: Objection.  
 11 THE WITNESS: I responded to  
 12 that. I don't know how to respond  
 13 again.  
 14 BY MR. SLATER:  
 15 Q. Well, you did, Doctor, just  
 16 what I heard was you told me what they  
 17 did and what regulators did. And I  
 18 literally did not ask you about what  
 19 anyone else did. I asked what would they  
 20 do. I asked what they were supposed to  
 21 do.  
 22 I just want to know if they  
 23 were supposed to look at that or not?  
 24 MS. DAVIDSON: Okay. So

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1 deposition behavior. Then when I  
 2 tried to explain that you were  
 3 interrupting Dr. Afnan, you  
 4 proceeded to interrupt me. So  
 5 you've now interrupted both of us  
 6 in the course of this. I was not  
 7 appreciative of that.  
 8 Please allow the witness to  
 9 finish answering questions he's  
 10 asked. Please do not interrupt  
 11 him.  
 12 I would object if there were  
 13 a question pending, but I don't  
 14 even know what question is pending  
 15 now. Because, basically, the  
 16 witness started to answer the  
 17 question and you berated --  
 18 interrupted and berated him.  
 19 So why don't we have the  
 20 court reporter read back the  
 21 question, and why doesn't  
 22 Dr. Afnan provide a complete  
 23 answer?  
 24 MR. SLATER: I'm not going

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1 to -- I'm going to ask the  
2 question again myself.

3 BY MR. SLATER:

4 Q. So, Dr. Afnan, do you agree  
5 that ZHP was required to assess the  
6 potential risks from the potential  
7 impurities that could be introduced to  
8 the zinc chloride process by the  
9 substances that ZHP was using; yes or no?

10 A. ZHP did do that. So yes.

11 But they did do that.

12 Q. I didn't ask if they did it.

13 I asked if they were supposed to do that.

14 Can you just answer that  
15 question, please?

16 A. I did answer.

17 MS. DAVIDSON: Objection.

18 Objection. Asked and answered.

19 BY MR. SLATER:

20 Q. Doctor, I would  
21 appreciate --

22 MS. DAVIDSON: You cannot  
23 control the way he answers a  
24 question. You can't, like, tell

1 A. I did.

2 Q. I'm not asking you what ZHP  
3 did. So I'm not sure why you're  
4 insisting on continually saying what ZHP  
5 did.

6 I asked what they were  
7 supposed to do. I didn't ask if they did  
8 it or not.

9 So can you please answer my  
10 question?

11 MS. DAVIDSON: I'm going to  
12 object again. Asked and answered.  
13 Compound question. Badgering the  
14 witness.

15 THE WITNESS: ZHP did what  
16 it was supposed to do.

17 BY MR. SLATER:

18 Q. Please answer my question.

19 I'm not asking what ZHP did.

20 Can you please answer my  
21 question about what they were supposed to  
22 do?

23 MS. DAVIDSON: Objection.  
24 We can stay on this all day if you

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1 him to repeat his question and cut  
2 off half the answer. Come on.

3 BY MR. SLATER:

4 Q. Doctor, I'm not asking you  
5 what ZHP actually did.

6 I asked you if they were  
7 supposed to evaluate the potential risks  
8 from the potential impurities that could  
9 be introduced to the zinc chloride  
10 process by the substances that ZHP was  
11 using.

12 I just want to know if  
13 that's something they were supposed to  
14 do. I'm not asking if they did it or  
15 not.

16 Can you please answer that  
17 question?

18 MS. DAVIDSON: Objection.  
19 Compound. And asked and answered.

20 THE WITNESS: ZHP did what  
21 it was supposed to do.

22 BY MR. SLATER:

23 Q. I'm sorry. Can you answer  
24 my question, please?

1 want. It's been asked and  
2 answered multiple times.

3 THE WITNESS: Yep. Yep.

4 BY MR. SLATER:

5 Q. I'm sorry, Doctor, that  
6 doesn't substitute for your answer. Just  
7 because counsel keeps talking and saying  
8 things. You have to actually answer the  
9 questions, under oath, yourself.

10 A. I answered the question that  
11 was asked, Mr. Slater.

12 My answer to you was ZHP  
13 followed the regulations, followed the  
14 GMPs, which sets the expectations, and  
15 carried out those activities.

16 Q. I keep telling you I'm not  
17 asking what ZHP did. I don't know why  
18 you keep telling me what ZHP did.

19 Am I not communicating  
20 clearly?

21 MS. DAVIDSON: Objection.  
22 I'm going to instruct you not to  
23 answer that question. That is  
24 not -- that is a rhetorical

<p>1 question. You're badgering the 2 witness.</p> <p>3 Come on, Adam, just ask your 4 questions and that's that. Don't 5 badger the witness.</p> <p>6 MR. SLATER: I don't really 7 want to talk directly with you at 8 this point about this. I really 9 just want to explain to him, since 10 it's his first deposition, that 11 when I keep asking one question 12 and he keeps talking about 13 something I'm not asking, I find 14 it to be, you know, a little bit 15 frustrating. I'm not yelling. 16 I'm talking in a normal tone of 17 voice.</p> <p>18 And I don't understand why 19 he keeps telling me what they did 20 when I've said, like, six times in 21 a row, I'm not asking what they 22 did. I'm asking what they're 23 supposed to do.</p> <p>24 So I'm starting -- I'm</p>	<p>Page 150</p> <p>1 that could be introduced to the zinc 2 chloride process by the substances that 3 ZHP was using?</p> <p>4 I want to know if they were 5 supposed to do that. I'm not asking what 6 they did. I'm asking if they were 7 supposed to do so.</p> <p>8 Can you please answer that 9 question?</p> <p>10 MS. DAVIDSON: Objection. 11 Vague. Asked and answered.</p> <p>12 Dr. Afnan, do you want the 13 question read back by the court 14 reporter?</p> <p>15 THE WITNESS: Sure.</p> <p>16 MR. SLATER: You need the 17 question read back?</p> <p>18 THE WITNESS: Yes, please.</p> <p>19 BY MR. SLATER:</p> <p>20 Q. Was ZHP required to assess 21 the potential risks that could be 22 introduced due to potential impurities 23 from the substances used in the zinc 24 chloride process; yes or no?</p>
<p>1 feeling like he won't answer my 2 question deliberately, which 3 doesn't feel good.</p> <p>4 So I'll give it one last 5 shot, and then we'll mark this 6 part of the transcript.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. Doctor, I'm not asking you 9 what ZHP did. I'm asking if they were 10 supposed to do what I asked you.</p> <p>11 Can you just answer that 12 question, please?</p> <p>13 MS. DAVIDSON: Objection. 14 Vague. Asked and answered. 15 Mischaracterizes his testimony. 16 I think that's it.</p> <p>17 THE WITNESS: Can you read 18 back the question that you keep 19 asking me, which I believe I have 20 answered?</p> <p>21 BY MR. SLATER:</p> <p>22 Q. Here is the question: Was 23 ZHP required to evaluate and assess the 24 potential risks from potential impurities</p>	<p>Page 151</p> <p>1 MS. DAVIDSON: Objection. 2 Vague. Asked and answered.</p> <p>3 THE WITNESS: ZHP looked at 4 the potential risks due to the 5 potential impurities in the 6 process, referring to the zinc 7 chloride process, and came to a 8 conclusion, which was reported to 9 FDA.</p> <p>10 ZHP did do what it was 11 supposed to do.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. Did I ask you what ZHP did 14 in that question?</p> <p>15 MS. DAVIDSON: Objection. 16 That's not a question to answer.</p> <p>17 MR. SLATER: It actually is 18 a question.</p> <p>19 BY MR. SLATER:</p> <p>20 Q. Please answer.</p> <p>21 MS. DAVIDSON: No.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. Doctor, did I ask you what 24 ZHP did or did I ask you, as I have,</p>

<p>1 like, multiple times, asked you what they 2 were supposed to do? 3 MS. DAVIDSON: Objection. 4 BY MR. SLATER: 5 Q. I mean, is my question not 6 clear? Are you not understanding my 7 question? If you're not then I can, you 8 know, rephrase it. 9 MS. DAVIDSON: Adam, every 10 time I object you just badger the 11 witness more. And so I don't even 12 know what question is pending. 13 And I'm objecting to your 14 follow-on badgering of the witness 15 following the badgering of the 16 witness I already objected to. 17 THE WITNESS: You want a 18 yes-or-no answer from me. I am 19 not able to give you a yes-or-no 20 answer, because I think the 21 question has no merit of a 22 yes-or-no answer -- or the answer 23 has no merit if it's a yes-or-no 24 answer.</p>	<p>Page 154</p> <p>1 Did you take that into 2 account, that those were both pathways to 3 degradation that could yield 4 dimethylamine? 5 MS. DAVIDSON: Objection. 6 THE WITNESS: Dr. Xue, who 7 is a synthesis organic chemist, a 8 respected lecturer at University 9 of Maryland, addresses those 10 issues -- those points, in his 11 testimony. 12 The thermal decomposition 13 that you have asked me about and 14 is on the screen is effectively 15 based on reaching a particular 16 temperature which the process was 17 never at. 18 So if that temperature is 19 not reached and if hydrolysis is 20 not taking place, because it's 21 neither acidic or basic, then -- 22 the question of did I take that 23 into account? The answer is, yes, 24 I did take that into account.</p> <p>Page 155</p>
<p>1 I believe I have answered 2 the question multiple times in 3 exact same manner and have 4 addressed the question you have 5 asked me. 6 BY MR. SLATER: 7 Q. Let's go now to Page 890 of 8 that document. Same document we've been 9 in, which is Exhibit-7. The very top. 10 At the top of Page 890, it 11 says, Tests for purity. Owing to its 12 various modes of degradation, hydrolysis, 13 thermal and photochemical decomposition, 14 the principal impurities found in DMF 15 are: dimethylamine, formic acid, 16 hydrogen cyanide, carbon dioxide and 17 carbon monoxide. 18 Do you see that? 19 A. I see it, yes. 20 Q. In forming your opinions in 21 this case, did you take into account the 22 fact that DMF could degrade through 23 hydrolysis and due to thermal impact, 24 meaning temperature?</p>	<p>Page 157</p> <p>1 BY MR. SLATER: 2 Q. Did you form your own 3 independent opinion about what you just 4 told me, or were you relying on Dr. Xue's 5 analysis of that subject matter? 6 A. Dr. Xue refers to two 7 statements. One is about the boiling 8 point of DMF, which I have referenced him 9 and verified by looking at, effectively, 10 the boiling point of DMF. I've also 11 looked at the pH of the process, which, 12 again, he refers to, and, again, I have 13 verified. 14 So is it my opinion or is it 15 his opinion? It's my opinion. 16 Q. And you are not an expert in 17 the field of organic chemistry, right? 18 A. I am -- 19 MS. DAVIDSON: Objection. 20 Objection. You literally 21 objected, Adam, last week every 22 single time I asked somebody if 23 they were an expert in something. 24 MR. SLATER: I'll ask the</p>

	Page 158		Page 160
1	question differently.	1	degrade and give off dimethylamine under
2	<b>BY MR. SLATER:</b>	2	the conditions of the zinc chloride
3	Q. You told me before that you	3	process.
4	are not holding yourself out as an expert	4	Do you know whether they did
5	in organic chemistry.	5	or not? Did they perform any test on
6	Have you changed your mind	6	that?
7	on that?	7	<b>MS. DAVIDSON:</b> Objection.
8	A. I have a degree in	8	<b>THE WITNESS:</b> I don't recall
9	chemistry. I have a Ph.D. in chemistry.	9	whether they did any tests or not.
10	I am not a synthetic organic	10	However, the common practice
11	chemist and up to date, but I do	11	of industry would have been to
12	understand sufficiently about chemistry	12	effectively look at known
13	to opine on the subject.	13	solvents. And this was a known
14	Q. In the materials you	14	solvent.
15	reviewed, did you see whether ZHP tested,	15	The risk assessment would
16	at any time, to see if DMF could degrade	16	have occurred -- the assessment
17	and yield dimethylamine under the	17	that you are asking would have
18	conditions used in the zinc chloride	18	occurred during development phases
19	process?	19	and not during commercial
20	<b>MS. DAVIDSON:</b> Objection.	20	manufacture.
21	<b>THE WITNESS:</b> So if I go to	21	The development phases were
22	my report, I think the answer is	22	done at a different site and they
23	there.	23	were investigated and studied over
24	Number 169, it says, and	24	the course of more than two years.
	Page 159		Page 161
1	it's the third line, But as	1	<b>BY MR. SLATER:</b>
2	Mr. Dong explains, this was	2	Q. Can you answer my question,
3	because both sodium azide and	3	please?
4	sodium nitrate had been used	4	A. I answered your question,
5	before the process changed, and	5	which was, did they look at this test,
6	ZHP concluded, through the risk	6	did they test for this?
7	assessment process, that the	7	And my answer is still, ZHP
8	increased amount of these	8	looked at the new process, the zinc
9	substances did not significantly	9	chloride process with DMF, over a period
10	increase the potential risk of	10	of longer than two years in the
11	sodium azide or sodium nitrate.	11	development workshop at a different site.
12	Moreover, even though ZHP had	12	And they concluded that the
13	concluded the potential risk was	13	process was not generating anything
14	low, it still conducted testing to	14	undesirable, so.
15	determine residual amounts of	15	Q. Could you please answer my
16	those substances and performed a	16	question?
17	further risk assessment based on	17	<b>MS. DAVIDSON:</b> Objection.
18	that testing.	18	<b>THE WITNESS:</b> I answered the
19	So they did look at what was	19	question.
20	going on.	20	ZHP, over two years,
21	<b>BY MR. SLATER:</b>	21	investigated the raw materials and
22	Q. I just asked you whether	22	the process at their development
23	ZHP, to your knowledge, ever performed	23	site and reported that data.
24	any tests to determine whether DMF could	24	<b>BY MR. SLATER:</b>

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1 Q. Can you answer my question,  
 2 please?

3 MS. DAVIDSON: Objection.  
 4 You're badgering the witness.  
 5 He's answered your question to the  
 6 best of his ability.

7 BY MR. SLATER:

8 Q. Please answer.

9 MS. DAVIDSON: Objection.

10 THE WITNESS: ZHP -- ZHP  
 11 tested all the raw materials and  
 12 the product from the process in  
 13 their development facility over a  
 14 period of greater -- longer than  
 15 two years.

16 BY MR. SLATER:

17 Q. Did ZHP ever, to your  
 18 knowledge, ever do a test to determine  
 19 whether, under the conditions of the zinc  
 20 chloride process, DMF could degrade and  
 21 give off dimethylamine; yes or no?

22 Was that specific test ever  
 23 done by ZHP, to your knowledge?

24 MS. DAVIDSON: Objection.

1 Mischaracterizes testimony.  
 2 Badgering the witness.

3 THE WITNESS: That's not  
 4 what I said. What I said was,  
 5 they -- raw materials that were  
 6 being used in the process were  
 7 reviewed, were assessed, were risk  
 8 assessed, for ensuring that the  
 9 process was safe.

10 MR. SLATER: Let's take that  
 11 exhibit down. And let's go back  
 12 to the deviation investigation  
 13 report, please. Page 170.

14 MS. DAVIDSON: What exhibit  
 15 number was that again? Could  
 16 someone remind me?

17 MR. SLATER: I don't  
 18 remember. It's either Exhibit-5  
 19 or 6. Why don't we find out.  
 20 Exhibit-5.

21 Actually, let's start off --  
 22 yeah. Okay. That's good.

23 BY MR. SLATER:

24 Q. Looking at page --

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1 Asked and answered.

2 THE WITNESS: I have  
 3 answered the question twice or  
 4 three times.

5 So did ZHP ever do it? As  
 6 I've said, they did it in their  
 7 development facility. In a  
 8 commercial setting, it would be  
 9 against the GMPs to begin to do  
 10 tests on the site for whatever  
 11 reason, whatever purpose.

12 BY MR. SLATER:

13 Q. Your testimony is that as  
 14 part of the risk assessment, ZHP  
 15 performed a specific test to determine  
 16 whether DMF could degrade and give off  
 17 dimethylamine under the conditions of the  
 18 zinc chloride process?

19 It's your understanding they  
 20 actually did that test as part of the  
 21 risk assessment; do I understand you  
 22 correctly?

23 MS. DAVIDSON: Objection.

24 Asked and answered.

1 MR. SLATER: Actually, you  
 2 know what, Chris, let's go back.  
 3 Let's go to Page 9, actually.  
 4 Sorry about that.

5 BY MR. SLATER:

6 Q. Okay. We're looking now at  
 7 Page 9 of Exhibit-5, the deviation  
 8 investigation report.

9 And I'd like to look  
 10 starting in the middle of the page. And  
 11 it says, For further confirmation, the  
 12 following lab scale trials were designed  
 13 and performed to verify the concluded  
 14 formation mechanism of NDMA. The amount  
 15 of NDMA formed by quenching under  
 16 different temperatures is shown in the  
 17 table below.

18 Have you seen this page and  
 19 taken this into account in forming your  
 20 opinions in this case?

21 A. Yes.

22 Q. So you were aware that, as  
 23 part of their deviation investigation,  
 24 ZHP actually did lab tests where they had

<p style="text-align: right;">Page 166</p> <p><sup>1</sup> DMF at the same temperature for the same <sup>2</sup> time period as under the zinc chloride <sup>3</sup> process and then, after that, combined <sup>4</sup> the sodium nitrate and they proved that <sup>5</sup> NDMA resulted; so you're aware of that, <sup>6</sup> correct?</p> <p><sup>7</sup> MS. DAVIDSON: Objection.</p> <p><sup>8</sup> THE WITNESS: This document <sup>9</sup> that you're looking at has some <sup>10</sup> differences from the commercial <sup>11</sup> scale batch.</p> <p><sup>12</sup> If you are looking at Rows <sup>13</sup> Number 1 and 2, it's actually <sup>14</sup> saying the pH is adjusted to 1. <sup>15</sup> So the commercial process <sup>16</sup> was not operating at pH of 1, <sup>17</sup> number one. <sup>18</sup> Number two, this is a test <sup>19</sup> where they are driving to make <sup>20</sup> NDMA. They are not trying to make <sup>21</sup> valsartan, they are trying to make <sup>22</sup> NDMA in the valsartan process. <sup>23</sup> Point three, this document <sup>24</sup> is after they have identified</p>	<p style="text-align: right;">Page 168</p> <p><sup>1</sup> DMF, at 135 degrees, okay, 20 hours, then <sup>2</sup> add MTB, water, sodium nitrate and adjust <sup>3</sup> to 1 and then quench it as zero degrees <sup>4</sup> and quench it at 10 and quench it at 20 <sup>5</sup> degrees. <sup>6</sup> So it's different settings <sup>7</sup> to generate or to create NDMA. That's <sup>8</sup> what this document says. <sup>9</sup> I don't see any statement <sup>10</sup> about dimethylamine.</p> <p><sup>11</sup> Q. How would the NDMA have <sup>12</sup> formed if the DMF didn't introduce the <sup>13</sup> dimethylamine?</p> <p><sup>14</sup> A. That is --</p> <p><sup>15</sup> MS. DAVIDSON: Objection.</p> <p><sup>16</sup> BY MR. SLATER:</p> <p><sup>17</sup> Q. You're the -- you said <sup>18</sup> you're a chemistry expert now, so tell <sup>19</sup> me -- let me ask the question <sup>20</sup> differently. <sup>21</sup> How did the NDMA -- <sup>22</sup> rephrase. <sup>23</sup> You see the fourth column, <sup>24</sup> it says, NDMA in parts per million? Do</p>
<p style="text-align: right;">Page 167</p> <p><sup>1</sup> NDMA. This document, this <sup>2</sup> deviation investigation, is <sup>3</sup> actually trying to find the root <sup>4</sup> cause of NDMA formation, and <sup>5</sup> they're trying various process <sup>6</sup> parameters to see what results <sup>7</sup> would come from that. This is <sup>8</sup> then reported to FDA.</p> <p><sup>9</sup> BY MR. SLATER:</p> <p><sup>10</sup> Q. All I asked you is if you <sup>11</sup> knew this information when you wrote your <sup>12</sup> report.</p> <p><sup>13</sup> Is the answer yes or no?</p> <p><sup>14</sup> MS. DAVIDSON: Objection.</p> <p><sup>15</sup> THE WITNESS: Did I read the <sup>16</sup> investigation report, yes.</p> <p><sup>17</sup> BY MR. SLATER:</p> <p><sup>18</sup> Q. And this showed that when <sup>19</sup> DMF was heated to 135 degrees Celsius for <sup>20</sup> 20 hours, it created dimethylamine, which <sup>21</sup> then later combined with the sodium <sup>22</sup> nitrate and NDMA was formed, correct? <sup>23</sup> That's what this lab test shows, right? <sup>24</sup> A. This lab test shows that if</p>	<p style="text-align: right;">Page 169</p> <p><sup>1</sup> you see that?</p> <p><sup>2</sup> A. Yes.</p> <p><sup>3</sup> Q. How did that NDMA form?</p> <p><sup>4</sup> MS. DAVIDSON: Objection. That's outside the scope of his opinions.</p> <p><sup>5</sup> MR. SLATER: When you say that, so I know how to take the deposition, are you saying he's not giving chemistry opinions? Because he just said a few minutes ago he is. So I need to understand what's in and what's out.</p> <p><sup>6</sup> MS. DAVIDSON: I didn't hear him say he's giving chemistry opinions. I think you're mischaracterizing his testimony now.</p> <p><sup>7</sup> I will let the witness speak for himself.</p> <p><sup>8</sup> THE WITNESS: I did not say that I was giving chemistry opinions. I said I do have a</p>

	Page 170	Page 172
1       chemistry background.		1 According to the deviation investigation
2           My expertise in this is		2 report, DCE18001, in tetrazole formation
3           GMPs. And, again, to re-tread the		3 of crude step, DMF is used as solvent and
4           point, I look at that screen and		4 zinc chloride is used as catalyst. Since
5           that tells me about the various		5 the temperature might reach 135, plus or
6           conditions ZHP created to see what		6 minus 5 degrees Celsius, and the reaction
7           the -- you know, what levels of		7 time period last for 20, plus or minus
8           NDMA are formed.		8 one hour, dimethylamine might be formed
9 BY MR. SLATER:		9 by decomposition of DMF.
10          Q. Do you have any		10           Do you see what I just read?
11          understanding as to how that NDMA formed		11          A. Yes.
12          in those lab tests, which you read about		12          Q. Do you disagree with that
13          before you authored your report?		13 conclusion that was drawn by ZHP in its
14          MS. DAVIDSON: Objection.		14 deviation investigation report that I
15 BY MR. SLATER:		15 just read to you?
16          Q. It's a yes or no. Either		16          A. This is not a conclusion,
17          you know or you don't.		17 because it's saying it's a probable root
18          MS. DAVIDSON: Objection. I		18 cause. It's using the word -- the
19          apologize for objecting in the		19 language, which says, and the reaction,
20          middle of your questions. I		20 it might be formed. That's not an, it is
21          always think they're done and then		21 formed.
22          there's a postscript.		22          This, as a deviation report,
23          THE WITNESS: My role, my		23 if submitted, which says it might be
24          remit, was to look at the		24 formed, my response would be, tell me
	Page 171	Page 173
1       plaintiff experts and assess		1 whether it is or it isn't.
2       GMP -- GMP statements.		2           And, again, this document is
3           I was not here, on this		3 with hindsight. This document is being
4           project, to assess the chemistry.		4 used to assess and to find the different
5           For that, there was Professor Xue.		5 pathways.
6           What I'm looking at and what		6           Now, it also says, if the
7           you asked me about this		7 temperature -- it says, the temperature
8           is whether, you know,		8 might reach 135, plus or minus 5 degrees.
9           dimethylamine is formed. And I'm		9 That information would be available in
10          saying, I don't see it on the		10 the batch report.
11          screen.		11          Q. Did you evaluate that issue
12 BY MR. SLATER:		12 at all, what temperatures were reached
13          Q. Do you doubt the results of		13 and what impact that could have on the
14          these tests for any reason as they're		14 DMF?
15          documented in this report from ZHP?		15          A. Again, my remit here was not
16          A. I have no evidence to doubt		16 chemistry.
17          these results. And these were the		17          Q. As a GMP expert, one of your
18          results which were also submitted to FDA.		18 rolls -- one of the things -- rephrase.
19           So, no, I don't doubt the		19          As a GMP expert, one of the
20          results.		20 things you needed to consider was what
21          Q. Let's go to Page 170 of that		21 tests were performed by ZHP to determine
22          document, please.		22 whether they performed tests that were
23           Looking now at the middle of		23 required by cGMP; that was within the
24          the page, ZHP states in this report,		24 scope of what you were doing, right?

<p style="text-align: right;">Page 174</p> <p>1 MS. DAVIDSON: Objection.      2 THE WITNESS: So the tests      3 which are required to be performed      4 for release of material are      5 defined as per USP. So those are      6 the tests which are there.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. Looking at the paragraph      9 that I was just reading in, it continues,      10 In subsequent step, when using sodium      11 nitrite to quench redundant azide,      12 valsartan was not separated.</p> <p>13 Do you understand what that      14 sentence means?</p> <p>15 MS. DAVIDSON: Objection.      16 THE WITNESS: So the      17 valsartan was not separated, as it      18 didn't settle out.</p> <p>19 BY MR. SLATER:</p> <p>20 Q. The next sentence says --      21 rephrase.</p> <p>22 Looking at the paragraph in      23 the middle of the page, after the first      24 couple of sentences about the formation</p>	<p style="text-align: right;">Page 176</p> <p>1 think you're delving into      2 chemistry at this point, which are      3 questions that are more      4 appropriately asked to Professor      5 Xue, who you already deposed.      6 But if you're just asking      7 about his GMP opinions, that's      8 fine.</p> <p>9 THE WITNESS: So can you ask      10 your question, please?</p> <p>11 BY MR. SLATER:</p> <p>12 Q. When you formed your      13 opinions in this case regarding cGMP, did      14 you take this information into account      15 that I just read to you?      16 I just want to know if you      17 took it into account when you formed your      18 opinions; yes or no?</p> <p>19 MS. DAVIDSON: Objection.      20 BY MR. SLATER:</p> <p>21 Q. And, by the way, Doctor, I'm      22 not asking for what the analysis was.      23 I'm just asking if you took it into      24 account.</p>
<p style="text-align: right;">Page 175</p> <p>1 of dimethylamine, it states, In      2 subsequent step when using sodium nitrite      3 to quench redundant azide, valsartan was      4 not separated. Thus, trace amount of      5 NDMA is formed by reaction between      6 dimethylamine and nitrous acid. To      7 verify this conclusion, Huahai conducted      8 simulation tests in the laboratory to      9 demonstrate the DMF degradation and the      10 generation of NDMA, the detail is in      11 Table 4-40 as follows.</p> <p>12 Do you see what I just read?</p> <p>13 A. I see what you just read.</p> <p>14 Q. Did you read that when you      15 wrote your report? Had you read that      16 information I just read to you?</p> <p>17 A. I have read this before I      18 wrote my report, yes.</p> <p>19 Q. Did you factor that into the      20 opinions you offered on GMP in this case;      21 yes or no?</p> <p>22 MS. DAVIDSON: I really -- I      23 guess if you're asking simply      24 about GMP, that's fine. I really</p>	<p style="text-align: right;">Page 177</p> <p>1 MS. DAVIDSON: I really      2 think we need to have one question      3 pending, one question answered,      4 because you just said six      5 different things.</p> <p>6 BY MR. SLATER:</p> <p>7 Q. You can answer.</p> <p>8 A. The challenge that I have      9 answering your complex and multiple      10 questions is you say, did I take this      11 into account when making my GMP      12 decisions?</p> <p>13 This is an investigation,      14 which is happening in a lab, in a lab      15 setting, as a result of a deviation which      16 has taken place before these activities      17 were taking place, before these -- this      18 data was being generated.</p> <p>19 The reason the data was      20 generated was to actually push the      21 process to certain limits and see what      22 the impact is. This is not happening in      23 a GMP setting, even though it's a      24 deviation investigation for a GMP</p>

<p>1 deviation.</p> <p>2 These are happening in a 3 development setting to try and address, 4 to try and understand how NDMA is formed.</p> <p>5 So when you ask me straight 6 questions expecting a yes-or-no answer, I 7 struggle.</p> <p>8 Q. When you formed your 9 opinions regarding whether or not ZHP 10 complied with cGMPs, was this information 11 that I just read to you something that 12 you factored into your opinion?</p> <p>13 Either it's yes or no or you 14 can say something like, it was 15 irrelevant, I didn't have to consider it.</p> <p>16 I don't know what your 17 answer is, but I'd just like to know if 18 it was something that you relied on, in 19 part, in forming your opinions.</p> <p>20 MS. DAVIDSON: I'm going to 21 object. Asked and answered.</p> <p>22 THE WITNESS: I have 23 answered this question.</p> <p>24 And when I'm reading this,</p>	<p>Page 178</p> <p>1 the zinc chloride process, right?</p> <p>2 A. This is happening with 3 hindsight, with effectively looking at -- 4 it's looking at what is happening in back 5 end of 2018 and not what was happening 6 early on.</p> <p>7 Early on, when they were 8 developing the process, ZHP had no reason 9 to vary the process parameters, as per 10 what's on the screen, and look for 11 formation of NDMA. Point one.</p> <p>12 Point two, as testified -- 13 or as stated by FDA, neither industry nor 14 the regulators knew about the chemical 15 pathways that would form NDMA.</p> <p>16 Point three, again, as is 17 stated by FDA, neither industry nor 18 regulators had the methods to detect 19 NDMA. Dr. Gottlieb specifically says, 20 NDMA is difficult to detect and to 21 isolate.</p> <p>22 So I look at this and this 23 is all after the event. This is with 24 hindsight. ZHP would not have known.</p>
<p>1 this is about an event which is 2 after GMP manufacturing has 3 stopped. ZHP stopped manufacture 4 of valsartan in June. This is 5 happening sometime later, much 6 later; and they're looking at it.</p> <p>7 This is not what was 8 happening in their GMP area. So 9 for me to look at this and look at 10 this data and to draw a conclusion 11 based on what was going on 12 beforehand would actually not be 13 correct.</p> <p>14 BY MR. SLATER:</p> <p>15 Q. You see in the Table 4-40 it 16 documents that, under these conditions 17 DMA was a degradation product of the DMF 18 under these conditions, correct? That's 19 what's documented on the table, correct?</p> <p>20 A. I see what the table says.</p> <p>21 Q. If ZHP had wanted to, they 22 could have run the same or similar lab 23 tests as part of their risk assessment 24 before they started manufacturing with</p>	<p>Page 179</p> <p>1 And, again, if ZHP -- the 2 fact that ZHP did not know about the 3 formation of NDMA is, again, stated by 4 the regulator. The regulators didn't 5 know that these processes would result in 6 NDMA.</p> <p>7 MR. SLATER: We can take 8 that document down now and go to a 9 different document.</p> <p>10 Is it 8 now, right? Did you 11 put it up? You were waiting for 12 me and I was waiting for you.</p> <p>13 MS. DAVIDSON: So we're 14 marking this as Exhibit-8?</p> <p>15 MR. SLATER: We are.</p> <p>16 - - -</p> <p>17 (Whereupon, Exhibit Afnan-8, 18 No Bates, 4/1/15 General Notices 19 and Requirements, was marked for 20 identification.)</p> <p>21 - - -</p> <p>22 MR. SLATER: Can you reduce 23 it just so the whole document is 24 on the page? Yeah. Perfect.</p>

<p style="text-align: right;">Page 182</p> <p><sup>1</sup> BY MR. SLATER:</p> <p><sup>2</sup> Q. So what we have on the <sup>3</sup> screen as Exhibit-8 is an April 1, 2015, <sup>4</sup> bulletin from the United States <sup>5</sup> Pharmacopeia convention titled, General <sup>6</sup> Notices and Requirements.</p> <p><sup>7</sup> Do you see that?</p> <p><sup>8</sup> A. Yes.</p> <p><sup>9</sup> Q. Do you know what USP is?</p> <p><sup>10</sup> A. Yes.</p> <p><sup>11</sup> Q. What is USP?</p> <p><sup>12</sup> A. USP is a not-for-profit <sup>13</sup> independent organization that effectively <sup>14</sup> writes two types of monographs. One is a <sup>15</sup> general chapter, which is binding. And <sup>16</sup> the other, which are not binding. So <sup>17</sup> they write the specifications.</p> <p><sup>18</sup> Q. When you say "they write the <sup>19</sup> specifications," what specifications?</p> <p><sup>20</sup> A. APIs, drug products, some <sup>21</sup> raw materials.</p> <p><sup>22</sup> Q. Let's go to Page 4, please. <sup>23</sup> And I'm looking now under <sup>24</sup> Section 5.60, titled, Impurities and</p>	<p style="text-align: right;">Page 184</p> <p><sup>1</sup> A. Yes.</p> <p><sup>2</sup> Q. Did you know what I just <sup>3</sup> read before I just read it to you?</p> <p><sup>4</sup> MS. DAVIDSON: Objection.</p> <p><sup>5</sup> MR. SLATER: I'm sorry, <sup>6</sup> what's the objection?</p> <p><sup>7</sup> MS. DAVIDSON: Does he know <sup>8</sup> what you read before you read it <sup>9</sup> to him? I don't even understand <sup>10</sup> that question.</p> <p><sup>11</sup> BY MR. SLATER:</p> <p><sup>12</sup> Q. Doctor, the information I <sup>13</sup> just read to you from this official USP <sup>14</sup> document, were you aware of that before I <sup>15</sup> read it to you, or is this the first time <sup>16</sup> you're seeing that?</p> <p><sup>17</sup> A. I was aware of that.</p> <p><sup>18</sup> Q. When they refer to a change <sup>19</sup> in the processing methods, here, with the <sup>20</sup> TEA and sodium nitrite quenching process <sup>21</sup> and the zinc chloride process, ZHP <sup>22</sup> changed the processing methods for <sup>23</sup> valsartan, correct?</p> <p><sup>24</sup> A. Yes.</p>
<p style="text-align: right;">Page 183</p> <p><sup>1</sup> Foreign Substances.</p> <p><sup>2</sup> Do you see that?</p> <p><sup>3</sup> A. Yes.</p> <p><sup>4</sup> Q. This says, Tests for the <sup>5</sup> presence of impurities and foreign <sup>6</sup> substances are provided to limit such <sup>7</sup> substances to amounts that are <sup>8</sup> unobjectionable under conditions in which <sup>9</sup> the article is customarily employed.</p> <p><sup>10</sup> Do you see what I just read?</p> <p><sup>11</sup> A. Yes.</p> <p><sup>12</sup> Q. Next this states,</p> <p><sup>13</sup> Non-monograph tests and acceptance <sup>14</sup> criteria suitable for detecting and <sup>15</sup> controlling impurities that may result <sup>16</sup> from a change in the processing methods <sup>17</sup> or that may be introduced from external <sup>18</sup> sources should be employed in addition to <sup>19</sup> the tests provided in the individual <sup>20</sup> monograph where the presence of the <sup>21</sup> impurity is inconsistent with applicable <sup>22</sup> good manufacturing practices or good <sup>23</sup> pharmaceutical practices.</p> <p><sup>24</sup> Do you see what I just read?</p>	<p style="text-align: right;">Page 185</p> <p><sup>1</sup> Q. When they refer to <sup>2</sup> impurities that may be introduced from <sup>3</sup> external sources, one way that impurity <sup>4</sup> can be introduced from an external source <sup>5</sup> would be, for example, with the DMF in <sup>6</sup> the zinc chloride process if the DMF, as <sup>7</sup> purchased, contained dimethylamine as an <sup>8</sup> impurity, correct?</p> <p><sup>9</sup> A. It could, yes.</p> <p><sup>10</sup> Q. And this is saying that in <sup>11</sup> those circumstances, non-monograph tests <sup>12</sup> and acceptance criteria should be <sup>13</sup> employed in addition to the tests <sup>14</sup> provided in the individual monograph <sup>15</sup> where the presence of the impurity is <sup>16</sup> inconsistent with applicable good <sup>17</sup> manufacturing practices or good <sup>18</sup> pharmaceutical practices.</p> <p><sup>19</sup> That's what it states, <sup>20</sup> correct?</p> <p><sup>21</sup> A. That's what it states.</p> <p><sup>22</sup> Q. The presence of NDMA and <sup>23</sup> NDEA in the valsartan manufactured by ZHP <sup>24</sup> was unwanted, correct?</p>

<p>1        A. Correct.</p> <p>2        Q. In fact, when it was</p> <p>3 discovered that the NDMA and NDEA were in</p> <p>4 the valsartan, that resulted in a recall</p> <p>5 of the finished-dose pills that had been</p> <p>6 manufactured with that API, correct?</p> <p>7        A. So the text you have read to</p> <p>8 me relates to impurities and not unknown</p> <p>9 impurities.</p> <p>10       The problem with NDMA, as</p> <p>11 stated by FDA, is that it's difficult to</p> <p>12 detect. The methods for its detection</p> <p>13 were not there. And that it was an</p> <p>14 unknown below a .1 percent, where ICH</p> <p>15 says you can have that impurity.</p> <p>16       The method which is used for</p> <p>17 effectively looking at the residual</p> <p>18 solvents, as is stipulated by the USP, is</p> <p>19 GC FID, that doesn't detect the NDMA.</p> <p>20       So if you know what you're</p> <p>21 looking for, then it is easy to go and</p> <p>22 look for it. But if one doesn't know</p> <p>23 what it's looking for, then it's very</p> <p>24 difficult to look for an unknown impurity</p>	<p>Page 186</p> <p>1 and ZHP followed Q3A.</p> <p>2       Q. The words on the page</p> <p>3 indicate that a manufacturer -- the word</p> <p>4 used is "should," should employ</p> <p>5 non-monograph tests and acceptance</p> <p>6 criteria where there's a change in the</p> <p>7 processing methods or impurities may be</p> <p>8 introduced from external sources.</p> <p>9       That's what the words on the</p> <p>10 page say, that you're not limited just to</p> <p>11 the tests and acceptance criteria listed</p> <p>12 in the monograph; that's what the words</p> <p>13 on the page say, correct?</p> <p>14       MS. DAVIDSON: Objection.</p> <p>15       THE WITNESS: So, again,</p> <p>16 I'll repeat.</p> <p>17       USP has no authority to say</p> <p>18 what -- to say to a manufacturer</p> <p>19 that you should do this. The same</p> <p>20 way that I have no authority when</p> <p>21 I say, Mr. Slater, please do not</p> <p>22 ask yes-or-no questions, okay.</p> <p>23 BY MR. SLATER:</p> <p>24       Q. Did I read the language</p>
<p>1 that you're not aware of.</p> <p>2       Q. The point of this section is</p> <p>3 instructing manufacturers that under</p> <p>4 certain circumstances, which we just went</p> <p>5 through, change in the processing methods</p> <p>6 or impurities that may be introduced from</p> <p>7 external sources, the manufacturer will</p> <p>8 need to develop and utilize non-monograph</p> <p>9 tests and acceptance criteria in order to</p> <p>10 address those circumstances; that's what</p> <p>11 this is saying, correct?</p> <p>12       MS. DAVIDSON: Objection.</p> <p>13       THE WITNESS: USP has no</p> <p>14 authority to -- to dictate to</p> <p>15 anyone what you have just read to</p> <p>16 me.</p> <p>17 BY MR. SLATER:</p> <p>18       Q. That's what the words on the</p> <p>19 page say, correct?</p> <p>20       A. Your statement was, this</p> <p>21 instruction. And my response is, USP</p> <p>22 cannot instruct industry what to do.</p> <p>23       However, industry followed</p> <p>24 Q3A, FDA adheres to Q3A, or follows that,</p>	<p>Page 187</p> <p>1 correctly?</p> <p>2       A. No, no, you didn't read the</p> <p>3 language incorrectly.</p> <p>4       What I'm saying is that it</p> <p>5 says should. That's advisory. That's</p> <p>6 not binding. That's -- USP has no</p> <p>7 authority to tell manufacturers what to</p> <p>8 do.</p> <p>9       Q3A is far more specific</p> <p>10 about what should be followed and should</p> <p>11 not be followed.</p> <p>12       Q. A manufacturer, such as ZHP,</p> <p>13 would be expected, at least as of April</p> <p>14 1, 2015, to understand that it would need</p> <p>15 to consider utilizing non-monograph tests</p> <p>16 and acceptance criteria as opposed to</p> <p>17 being limited by the USP tests and</p> <p>18 acceptance criteria in the monograph;</p> <p>19 that you'll agree to, that's what this</p> <p>20 provided -- that's what this information</p> <p>21 instructed or advised -- I'll start over,</p> <p>22 actually. Because I don't want to fall</p> <p>23 into the same back-and-forth with you.</p> <p>24       You would agree with me that</p>

<p>Page 190</p> <p>1 current good manufacturing practices, at      2 least as of April 1, 2015, required the      3 use of non-monograph tests and acceptance      4 criteria suitable for detecting and      5 controlling impurities that may result      6 from a change in the processing methods      7 or that may be introduced from external      8 sources? That is something that      9 manufacturers would have needed to      10 understand, right?</p> <p>11 A. As of January 2015, which is      12 the date of this document, this document      13 does not have any authority to stipulate      14 to manufacturers that they need to use      15 compendial or non-compendial tests, one.</p> <p>16 Two, this is referring to      17 known impurities.</p> <p>18 Three, unknown impurities,      19 unknown impurities, which by nature, by      20 their name, are unknown, which are not      21 expected to have an adverse -- to be --      22 to be carcinogenic, if one does not know      23 of the presence of such impurities and      24 the impurity is below .1 percent, as per</p>	<p>Page 192</p> <p>1 in ZHP's valsartan without doing a test?      2 MS. DAVIDSON: Objection.      3 THE WITNESS: As per FDA and      4 USP, USP's monograph for valsartan      5 requires the use of GC FID. It      6 required the use of GC FID then.      7 It requires use of GC FID today,      8 in 2023.</p> <p>9 FDA also stated,      10 acknowledged, that neither      11 industry nor regulators had the      12 test methods suitable for      13 detecting NDMA in valsartan. And      14 for that reason, FDA developed      15 those methods and published those      16 methods.</p> <p>17 BY MR. SLATER:</p> <p>18 Q. How would one have      19 identified NDMA in valsartan without      20 doing a test to confirm that there was      21 NDMA in valsartan?</p> <p>22 A. I've answered that question,      23 and I'll answer again.</p> <p>24 The methods, which were</p>
<p>Page 191</p> <p>1 ICH 3A, one need not look for that.</p> <p>2 Q. Where does it say unknown      3 impurities there? Where do you see      4 unknown?</p> <p>5 A. My point is --</p> <p>6 MS. DAVIDSON: Objection.</p> <p>7 Hold on, Dr. Afnan.</p> <p>8 I know I didn't object for,      9 like, three questions, you got out      10 of practice.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. Where does the word      13 "unknown" describe the impurities?</p> <p>14 A. It says, Non-monograph tests      15 and acceptance criteria suitable for      16 detecting and controlling impurities.</p> <p>17 If an impurity is unknown      18 and below .1 percent concentration and      19 not anticipated to be in a cohort of      20 concern, then there is no requirement, as      21 per Q3, to look for it, to isolate it, to      22 identify it, and then to come up with      23 non-compendial methods to detect it.</p> <p>24 Q. How would you identify NDMA</p>	<p>Page 193</p> <p>1 current up through June of 2018, in      2 industry did not actually indicate      3 presence of NDMA. As Dr. Gottlieb      4 stated, it's a very difficult substance      5 to detect. It's -- the methods are not      6 there and -- the methods are not there      7 and, also, they -- the substance is      8 difficult to detect. It's a residual      9 solvent, so it needs to be taken out of      10 solution into a gas and then tested.</p> <p>11 Q. Is there any other way to      12 confirm whether or not there's NDMA in      13 valsartan without running a test?</p> <p>14 It's a yes-or-no question.</p> <p>15 I just want to know, can you do it      16 without using a test?</p> <p>17 MS. DAVIDSON: Objection.</p> <p>18 THE WITNESS: If a firm      19 anticipated, and I'll use the word      20 firm, FDA, if it's anticipated      21 that had the NDMA would occur,      22 then they would look for it.</p> <p>23 But, again, if I go to the      24 FDA's 30th of August 2019</p>

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1 statement, it says, Because it was  
2 not anticipated that NDMA would  
3 occur at these levels in the  
4 manufacture of the valsartan API,  
5 manufacturers would not have been  
6 testing for it. They would not  
7 have records that helped identify  
8 the issue during the -- during an  
9 inspection.

10 So this particular risk  
11 would not have been identified on  
12 an inspection. FDA agrees that  
13 NDMA was not anticipated.

14 BY MR. SLATER:

15 Q. It's your opinion that as a  
16 matter of cGMP, ZHP did not have to run  
17 any tests to determine if there was NDMA  
18 or NDEA in its valsartan unless and until  
19 it anticipated that there would be NDMA  
20 or NDEA present in the valsartan?

21 MS. DAVIDSON: Objection.

22 THE WITNESS: Can you read  
23 the question again? Or can you  
24 repeat the question? One or the

1 THE WITNESS: So can you  
2 please repeat? I apologize,  
3 sincerely apologize to you, but  
4 can you repeat the question,  
5 please?

6 MS. DAVIDSON: It was a long  
7 question. You don't have to  
8 apologize.

9 BY MR. SLATER:

10 Q. If ZHP had actually  
11 identified the potential formation of  
12 NDMA or NDEA in its valsartan  
13 manufacturing processes and knew that  
14 that was a possible impurity that could  
15 be created by those processes, under  
16 those circumstances, would GMP have  
17 required ZHP to run tests to see if there  
18 was NDMA or NDEA in the valsartan?

19 A. Yes. But that's not the  
20 case here.

21 Q. We know from the documents I  
22 showed you before that ZHP should have  
23 anticipated at least the potential  
24 presence of dimethylamine in the zinc

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1 other.

2 BY MR. SLATER:

3 Q. Is it your opinion that ZHP  
4 did not have to test for NDMA or NDEA in  
5 its valsartan until it actually  
6 anticipated that there was NDMA or NDEA  
7 present in the valsartan?

8 A. So as per ICH guidances, if  
9 presence of NDMA, or any other mutagenic  
10 substance, is not anticipated, then there  
11 is no test to be done for it.

12 Q. That's your understanding of  
13 ICH?

14 A. Yes.

15 Q. If ZHP had determined, based  
16 on an analysis of the potential chemical  
17 reactions and the potential presence of  
18 secondary amines and nitrous acid in its  
19 valsartan manufacturing processes, under  
20 those circumstances, would GMP have  
21 required ZHP to then run a test to see if  
22 there actually was NDMA or NDEA in the  
23 valsartan?

24 MS. DAVIDSON: Objection.

1 chloride process, because we know that  
2 that's a known impurity of commercial  
3 DMF; we've established that, right?

4 MS. DAVIDSON: Objection.

5 THE WITNESS: No, we have  
6 not. I did not agree to that.

7 BY MR. SLATER:

8 Q. You disagree or do you have  
9 no opinion?

10 Tell me what your opinion is  
11 on that.

12 MS. DAVIDSON: Objection.

13 BY MR. SLATER:

14 Q. Let me ask the question  
15 clearly.

16 A. Okay.

17 Q. Are you saying that you  
18 disagree that ZHP should have been on  
19 notice of the potential for dimethylamine  
20 to be an impurity of the DMF it was  
21 purchasing? Are you saying they didn't  
22 have to be aware of that as a  
23 possibility?

24 MS. DAVIDSON: Objection.

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1 That was a compound question  
 2 again. When you say "are you  
 3 saying," I think you're  
 4 characterizing testimony, in which  
 5 case it was mischaracterized.

6 I really think this would go  
 7 more smoothly if you stuck to one  
 8 question at a time.

9 MR. SLATER: We're dealing  
 10 with a country lawyer who is  
 11 struggling through it. I'm doing  
 12 the best I can.

13 MS. DAVIDSON: From the  
 14 country of New Jersey?

15 All right. Dr. Afnan, I'm  
 16 sorry for the side show. Do you  
 17 understand the question you're  
 18 being asked right now or do you  
 19 need one question repeated to you?

20 THE WITNESS: It's a very --  
 21 BY MR. SLATER:

22 Q. You're obviously struggling  
 23 with it.

24 Let me do the best I can,

1 answer, and you stopped him and  
 2 interrupted him. I don't know  
 3 what his answer was going to be.

4 MR. SLATER: Counsel, all I  
 5 asked was if he has an opinion on  
 6 that. I didn't ask what it was.

7 MS. DAVIDSON: I understand.

8 MR. SLATER: So I'm entitled  
 9 to the answer to the question.

10 MS. DAVIDSON: That does not  
 11 entitle you to interrupt someone  
 12 mid question -- mid answer, Adam,  
 13 you know that.

14 And you wouldn't put up with  
 15 that if I were to do the same.

16 MR. SLATER: Please stop  
 17 talking. I'm just saying, you've  
 18 talked a lot and it's taking a lot  
 19 of time.

20 BY MR. SLATER:

21 Q. Just answer the question,  
 22 Doctor.

23 MS. DAVIDSON: What question  
 24 is pending? Because I don't know.

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1 because I obviously am struggling here,  
 2 too. Because I can't get an answer, so  
 3 it's obvious that my questions are no  
 4 good.

5 Do you have an opinion, one  
 6 way or the other, as to whether or not  
 7 ZHP should have been aware of the  
 8 potential for dimethylamine to be an  
 9 impurity of the DMF it was using in the  
 10 zinc chloride process? I just want to  
 11 know right now if you have an opinion on  
 12 that.

13 A. ZHP was not aware --

14 Q. Do you have an opinion on  
 15 the question --

16 MS. DAVIDSON: Whoa. No.  
 17 He was in the middle of a  
 18 sentence, Adam. Come on.

19 MR. SLATER: So you're  
 20 encouraging your witness not to  
 21 answer with a direct answer?  
 22 Okay. Thank you.

23 MS. DAVIDSON: What do you  
 24 mean? He was in the middle of an

1 MR. SLATER: I'm sorry you  
 2 lost track, but you're not the  
 3 person I'm deposing.

4 BY MR. SLATER:

5 Q. So please answer the  
 6 question.

7 MS. DAVIDSON: I'm asking  
 8 the court reporter to repeat the  
 9 question so we know what the  
 10 question is.

11 MR. SLATER: We're not going  
 12 to have the court reporter repeat  
 13 the question.

14 BY MR. SLATER:

15 Q. Doctor, do you, yes or no,  
 16 have an opinion, I just want to know if  
 17 you have an opinion, I don't want to know  
 18 what it is, as to whether or not ZHP  
 19 should have been aware of the potential  
 20 for dimethylamine to be an impurity of  
 21 the DMF it was using in the zinc chloride  
 22 process; yes or no? Do you have an  
 23 opinion?

24 MS. DAVIDSON: Objection.

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1 Objection. To all three questions  
 2 that were just combined into one.

3 THE WITNESS: I can't answer  
 4 that. I genuinely cannot answer  
 5 that.

6 MS. DAVIDSON: We've been  
 7 going a little more than an hour.  
 8 So, Adam, when you're at a  
 9 stopping point --

10 MR. SLATER: I'm not there  
 11 yet.

12 MS. DAVIDSON: What do you  
 13 mean?

14 MR. SLATER: I'm not at a  
 15 stopping point right now.

16 MS. DAVIDSON: Do you have  
 17 one or two questions on the same  
 18 topic --

19 MR. SLATER: I'm not going  
 20 to be -- look, you can walk out of  
 21 the deposition and take a break  
 22 whenever you want. But I'm in the  
 23 middle of a line of questioning.  
 24 There's no rule in the world that

1 I'm in the middle of asking.  
 2 You're now trying to stop me from  
 3 continuing. I don't think that's  
 4 kosher.

5 Can I please finish this  
 6 line of questioning? You're  
 7 wasting my time. And I don't  
 8 appreciate it.

9 MS. DAVIDSON: Dr. Afnan --

10 BY MR. SLATER:

11 Q. Doctor, do you know whether  
 12 or not ZHP knew that dimethylamine was a  
 13 potential impurity of the DMF it was  
 14 using in the zinc chloride process? Do  
 15 you know whether they knew about that or  
 16 not?

17 MS. DAVIDSON: Objection.

18 THE WITNESS: I do not  
 19 recall, and I would need to look  
 20 at the documentation to say yeah  
 21 or nay.

22 And I would like a break.

23 BY MR. SLATER:

24 Q. If ZHP knew --

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1 says every hour we take a long  
 2 break. I want to finish this line  
 3 of questioning.

4 I'm not agreeing to a break  
 5 right now.

6 MS. DAVIDSON: First of  
 7 all --

8 MR. SLATER: You know what,  
 9 I don't want to talk to you,  
 10 honestly, about this. I'm not  
 11 ready to break. I'm in the middle  
 12 of a line of questions, so it's  
 13 not a good stopping time.

14 I will now continue, unless  
 15 you stop the deposition and walk  
 16 out with your witness, and then  
 17 I'll have to wait for you to come  
 18 back.

19 MS. DAVIDSON: So two  
 20 things. Dr. Afnan, do you need a  
 21 break or do you want to go a few  
 22 more minutes?

23 MR. SLATER: I'm in the  
 24 middle -- there's a question that

1 MS. DAVIDSON: Whoa. He  
 2 just said he wants a break, so  
 3 let's take the break and follow up  
 4 afterwards.

5 MR. SLATER: Off the record  
 6 at defense counsel's insistence.

7 VIDEO TECHNICIAN: We're off  
 8 the record at 1:55 p.m.

9 - - -  
 10 (Whereupon, a brief recess  
 11 was taken.)

12 - - -  
 13 VIDEO TECHNICIAN: We're  
 14 back on the record at 2:07 p.m.

15 BY MR. SLATER:

16 Q. To be very clear, Dr. Afnan,  
 17 are you relying on Dr. Xue in order to  
 18 form any of your opinions?

19 Is there anything that  
 20 Dr. Xue has opined on where you would  
 21 say, I'm relying on that opinion in order  
 22 to form this other opinion?

23 MS. DAVIDSON: Objection.  
 24 THE WITNESS: So if I go to

<p>Page 206</p> <p>1 Statement Number 190 of my report, 2 okay, it's regarding the July 2017 3 e-mail, which the word "rely" 4 is -- I refer to his statement.</p> <p>5 But, again, I have verified 6 it by studying the -- Ms. Jucai 7 Ge's testimony on the subject.</p> <p>8 BY MR. SLATER:</p> <p>9 Q. So this is where you 10 referred to as detailed in the report of 11 Fengtian Xue, an expert chemist with 12 native fluency in Chinese, plaintiffs' 13 experts misread this highly technical 14 e-mail?</p> <p>15 A. Yes.</p> <p>16 Q. And am I understanding 17 correctly that one of the reasons you're 18 relying on Dr. Xue is because it's your 19 understanding that he is fluent in 20 Chinese?</p> <p>21 MS. DAVIDSON: Objection.</p> <p>22 THE WITNESS: As I said, I 23 verified by reading Jucai Ge's 24 testimony where she is questioned</p>	<p>Page 208</p> <p>1 A. Yes. 2 Q. What day was that? 3 A. I don't remember. Maybe 4 November, maybe December. It was before 5 my report. 6 Q. How many times did you speak 7 to her? 8 A. Once. 9 Q. How long did you speak to 10 her for? 11 A. I do not remember. 12 Q. Did you record the 13 conversation? 14 A. No. 15 Q. Did you take notes of the 16 conversation? 17 A. No. 18 Q. Do you remember what she 19 told you? 20 A. I remember what I asked and 21 what she told me. 22 Q. What was that? 23 A. I asked about customer 24 complaints or customer questions about</p>
<p>Page 207</p> <p>1 extensively about the e-mail.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. So you're not relying on 4 Dr. Xue at all?</p> <p>5 A. As I said --</p> <p>6 MS. DAVIDSON: Objection. 7 Hold on Dr. Afnan.</p> <p>8 THE WITNESS: For me to form 9 an opinion, okay, for me to form 10 an opinion on the subject, I've 11 looked at that e-mail, I've looked 12 at Jucai Ge's statement, I've 13 looked at -- sorry, deposition. I 14 have looked at all of those. And 15 I have also considered this.</p> <p>16 If you ask me which is the 17 document that I am putting the 18 most weight on, that's Jucai Ge's 19 testimony -- or not testimony, 20 deposition.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. I notice that you spoke to 23 Jucai Ge Ge, according to your report. 24 Did I read that correctly?</p>	<p>Page 209</p> <p>1 unknown peaks.</p> <p>2 Q. When you say you gave the 3 most weight to Jucai Ge's deposition, 4 what in particular about her deposition 5 did you put weight on with regard to your 6 understanding of the July 27, 2017, 7 e-mail?</p> <p>8 A. As she said in her 9 deposition of April 2022, she had 10 actually done -- you know, she said, I 11 prepared for the deposition, I went back 12 and read the e-mail, I studied the 13 e-mail. So she had actually done 14 background search regarding the e-mail.</p> <p>15 Q. You said you read the 16 e-mail.</p> <p>17 Did you read the e-mail in 18 English or in Chinese?</p> <p>19 A. English.</p> <p>20 Q. Which version?</p> <p>21 A. The version that was in the 22 plaintiff experts' references as exhibits 23 to plaintiff experts.</p> <p>24 Q. Did you read the testimony</p>

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<sup>1</sup> of Dr. Min Lee where he testified, on  
<sup>2</sup> behalf of ZHP, has to what the e-mail  
<sup>3</sup> said?

<sup>4</sup> A. I do recall some of the  
<sup>5</sup> depositions of Dr. Lee.

<sup>6</sup> Q. Was Dr. Lee's reading of the  
<sup>7</sup> e-mail of any significance to you in  
<sup>8</sup> forming your opinions about that e-mail?

<sup>9</sup> MS. DAVIDSON: Objection.  
<sup>10</sup> THE WITNESS: So Dr. Lee's  
<sup>11</sup> deposition was -- his statements  
<sup>12</sup> were not as detailed or as  
<sup>13</sup> informed as Jucai Ge Ge's.

<sup>14</sup> BY MR. SLATER:

<sup>15</sup> Q. Did you read John Du's  
<sup>16</sup> deposition and his testimony as to what  
<sup>17</sup> the e-mail said?

<sup>18</sup> A. I read that some time back.

<sup>19</sup> Q. Was John Du's testimony as  
<sup>20</sup> to what the e-mail said of significance  
<sup>21</sup> to you in forming your opinions about the  
<sup>22</sup> e-mail?

<sup>23</sup> MS. DAVIDSON: Objection.  
<sup>24</sup> THE WITNESS: I read a lot

<sup>1</sup> Q. I understand you looked at a  
<sup>2</sup> lot of materials.

<sup>3</sup> I'm asking if your reading  
<sup>4</sup> of John Du's testimony, as to what the  
<sup>5</sup> e-mail said, was significant to you in  
<sup>6</sup> forming your opinion?

<sup>7</sup> MS. DAVIDSON: Objection.

<sup>8</sup> THE WITNESS: I read a lot  
<sup>9</sup> of materials, including John Du's,  
<sup>10</sup> to then come to a conclusion.

<sup>11</sup> BY MR. SLATER:

<sup>12</sup> Q. Did you read the translation  
<sup>13</sup> of the e-mail that was provided by ZHP to  
<sup>14</sup> us in the litigation?

<sup>15</sup> A. I read the translation that  
<sup>16</sup> was submitted as evidence of the  
<sup>17</sup> plaintiff experts.

<sup>18</sup> Q. You don't know what the  
<sup>19</sup> e-mail said yourself, you have to rely on  
<sup>20</sup> other people to tell you what it said,  
<sup>21</sup> right?

<sup>22</sup> MS. DAVIDSON: Objection.

<sup>23</sup> BY MR. SLATER:

<sup>24</sup> Q. You can't read the e-mail in

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<sup>1</sup> of material to form an opinion  
<sup>2</sup> about the e-mail and to then make  
<sup>3</sup> a statement.

<sup>4</sup> BY MR. SLATER:

<sup>5</sup> Q. Was John Du's testimony in  
<sup>6</sup> regard to what the e-mail said  
<sup>7</sup> significant to you in forming your  
<sup>8</sup> opinion about the e-mail?

<sup>9</sup> MS. DAVIDSON: Objection.

<sup>10</sup> THE WITNESS: Would it be  
<sup>11</sup> possible for you to tell me what  
<sup>12</sup> you mean by "significance"?

<sup>13</sup> BY MR. SLATER:

<sup>14</sup> Q. Something that you would say  
<sup>15</sup> that's part of the reason why I formed my  
<sup>16</sup> opinion is because based on what John Du  
<sup>17</sup> said; I'm relying on what John Du said as  
<sup>18</sup> part of the basis for my opinion.

<sup>19</sup> A. So based on that, I'll give  
<sup>20</sup> the answer that I've already given.

<sup>21</sup> I looked at a lot of  
<sup>22</sup> depositions and materials regarding the  
<sup>23</sup> e-mail before I concluded my statement  
<sup>24</sup> which is in my report.

<sup>1</sup> Chinese -- new question.

<sup>2</sup> Since you can't read the  
<sup>3</sup> e-mail, as it was written in Chinese, you  
<sup>4</sup> have to rely on the accuracy of  
<sup>5</sup> translations by other people and the  
<sup>6</sup> testimony of other people as to what it  
<sup>7</sup> said, correct?

<sup>8</sup> MS. DAVIDSON: Objection.

<sup>9</sup> THE WITNESS: So I don't  
<sup>10</sup> speak Chinese. I read it in  
<sup>11</sup> English. I read the testimony --  
<sup>12</sup> the deposition, not testimony, the  
<sup>13</sup> deposition of Jucai Ge, which is  
<sup>14</sup> quite detailed, and she provides  
<sup>15</sup> far more information than anybody  
<sup>16</sup> else about the e-mail.

<sup>17</sup> I also looked at what  
<sup>18</sup> Dr. Xue says in his testimony,  
<sup>19</sup> which I have then referenced in my  
<sup>20</sup> statement.

<sup>21</sup> BY MR. SLATER:

<sup>22</sup> Q. Since you can't read the  
<sup>23</sup> e-mail yourself, as it was written in  
<sup>24</sup> Chinese, you have to rely on other people

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<sup>1</sup> to tell you what it said, correct?

<sup>2</sup> MS. DAVIDSON: Objection.  
<sup>3</sup> THE WITNESS: So there is a  
<sup>4</sup> translation. I read the  
<sup>5</sup> translation and I looked at that  
<sup>6</sup> translation in English.

<sup>7</sup> There is nobody pointing me  
<sup>8</sup> and saying, you know what, as you  
<sup>9</sup> read this, it means this, that or  
<sup>10</sup> the other. And that's why I was  
<sup>11</sup> most interested in Jucai Ge's  
<sup>12</sup> deposition, because that's quite  
<sup>13</sup> detailed.

<sup>14</sup> BY MR. SLATER:

<sup>15</sup> Q. Doctor, I'm honestly not  
<sup>16</sup> sure why it is that this question is  
<sup>17</sup> creating so much difficulty. It's  
<sup>18</sup> literally a foundational question to move  
<sup>19</sup> forward.

<sup>20</sup> You have to rely on the  
<sup>21</sup> translation of the e-mail and the  
<sup>22</sup> testimony of other people to understand  
<sup>23</sup> what the e-mail said, it's not something  
<sup>24</sup> you can read firsthand as written,

<sup>1</sup> deposition and Dr. Xue's report; that's  
<sup>2</sup> the basis for your understanding of what  
<sup>3</sup> it says, correct?

<sup>4</sup> A. And the text of the  
<sup>5</sup> translated text, as well as the  
<sup>6</sup> attachment that it refers to.

<sup>7</sup> Q. I want to understand if you  
<sup>8</sup> have a certain understanding of the  
<sup>9</sup> e-mail, okay?

<sup>10</sup> So I'm just asking, do you  
<sup>11</sup> understand it to say a certain thing?  
<sup>12</sup> That's all my question is. I'm not  
<sup>13</sup> asking for a speech. I'm not asking  
<sup>14</sup> about anybody else on earth.

<sup>15</sup> I know that you're smiling  
<sup>16</sup> and you're laughing, but I'm not asking  
<sup>17</sup> about anything else. So please don't  
<sup>18</sup> tell me about anything else so we can  
<sup>19</sup> actually use my time efficiently, because  
<sup>20</sup> I want to finish your deposition today.

<sup>21</sup> So please show me that  
<sup>22</sup> respect that you'll just answer my  
<sup>23</sup> question.

<sup>24</sup> MS. DAVIDSON: I'm going to

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<sup>1</sup> because you don't read Chinese, correct?

<sup>2</sup> MS. DAVIDSON: Objection.  
<sup>3</sup> THE WITNESS: I do not read  
<sup>4</sup> Chinese. And, again, as Jucai Ge  
<sup>5</sup> says, the e-mail is confusing, it  
<sup>6</sup> badly written, and she is reading  
<sup>7</sup> it in Chinese.

<sup>8</sup> So, no, I'm not reading  
<sup>9</sup> Chinese. I'm reading the  
<sup>10</sup> translation that was provided in  
<sup>11</sup> the plaintiff experts -- by the  
<sup>12</sup> plaintiff experts.

<sup>13</sup> BY MR. SLATER:

<sup>14</sup> Q. Your only basis to say the  
<sup>15</sup> e-mail is confusing and badly written is  
<sup>16</sup> Jucai Ge saying that in testimony, right?

<sup>17</sup> You have to rely on her for that, right?

<sup>18</sup> A. She says that, Dr. Xue says  
<sup>19</sup> that. Jucai Ge talked to Dr. Lin, who  
<sup>20</sup> was the author, and the author says, no,  
<sup>21</sup> that's not what I said.

<sup>22</sup> Q. If I understand correctly,  
<sup>23</sup> your understanding of what the e-mail  
<sup>24</sup> says really comes from Jucai Ge's

<sup>1</sup> object to that colloquy. I'm  
<sup>2</sup> objecting to that colloquy.  
<sup>3</sup> You're badgering.

<sup>4</sup> MR. SLATER: You can object.  
<sup>5</sup> I'm going to continue.

<sup>6</sup> MS. DAVIDSON: You're  
<sup>7</sup> interrupting me. Please do not  
<sup>8</sup> badger the witness. Please do not  
<sup>9</sup> speak to the witness that way.  
<sup>10</sup> You're asking the witness to show  
<sup>11</sup> you respect, so show respect to  
<sup>12</sup> the witness.

<sup>13</sup> Thank you.

<sup>14</sup> MR. SLATER: Thank you very  
<sup>15</sup> much for those instructions. I  
<sup>16</sup> appreciate it.

<sup>17</sup> BY MR. SLATER:

<sup>18</sup> Q. Does your -- rephrase.

<sup>19</sup> Do you understand the e-mail  
<sup>20</sup> to say, in part, that there is NDMA in  
<sup>21</sup> valsartan; yes or no?

<sup>22</sup> A. The e-mail, based on the  
<sup>23</sup> translation that I have seen, as well as  
<sup>24</sup> the patent which was accompanied with it,

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<sup>1</sup> alone without anything else, does not  
<sup>2</sup> tell me there is NDMA in valsartan.

<sup>3</sup> I have supporting evidence  
<sup>4</sup> from Jucai Ge and Dr. Xue, and others,  
<sup>5</sup> that effectively says that's not the  
<sup>6</sup> statement that the e-mail is making.

<sup>7</sup> Q. Who are the others?

<sup>8</sup> A. There are others who have  
<sup>9</sup> been deposed.

<sup>10</sup> Q. Who else said that it  
<sup>11</sup> doesn't say that there's NDMA in  
<sup>12</sup> valsartan?

<sup>13</sup> A. The two -- the two others  
<sup>14</sup> that I cannot recall right now that you  
<sup>15</sup> mentioned.

<sup>16</sup> Q. You think that Min Lee and  
<sup>17</sup> John Du said that the e-mail does not  
<sup>18</sup> indicate that there's NDMA in valsartan?  
<sup>19</sup> You think that's their testimony under  
<sup>20</sup> oath?

<sup>21</sup> MS. DAVIDSON: Objection.

<sup>22</sup> THE WITNESS: Yes.

<sup>23</sup> BY MR. SLATER:

<sup>24</sup> Q. Is it your understanding

translation of the e-mail? Are  
you referring to the e-mail?

<sup>3</sup> MR. SLATER: I'm referring  
to the e-mail.

<sup>5</sup> MS. DAVIDSON: The e-mail in  
Chinese?

<sup>7</sup> MR. SLATER: Counsel, I'm  
<sup>8</sup> not going to go back-and-forth  
<sup>9</sup> with you. Just -- you objected to  
<sup>10</sup> the form of the question. Please  
<sup>11</sup> answer.

<sup>12</sup> I'm done with these  
<sup>13</sup> discussions with you. I have  
<sup>14</sup> three more hours on the record.  
<sup>15</sup> I'm not going to spend it talking  
<sup>16</sup> to you.

<sup>17</sup> BY MR. SLATER:

<sup>18</sup> Q. Please answer the question,  
<sup>19</sup> Doctor.

<sup>20</sup> A. Can I please get the e-mail  
<sup>21</sup> on the screen?

<sup>22</sup> Q. Sure. One second.

<sup>23</sup> A. Thank you.

<sup>24</sup> Q. I'm going to get you the

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<sup>1</sup> that the e-mail indicates that the NDMA  
<sup>2</sup> in the valsartan was caused by the  
<sup>3</sup> quenching with sodium nitrite?

<sup>4</sup> MS. DAVIDSON: Objection.

<sup>5</sup> THE WITNESS: The e-mail is  
<sup>6</sup> talking about Impurity K, it's not  
<sup>7</sup> talking about NDMA. It's taking  
<sup>8</sup> about irbesartan process. And  
<sup>9</sup> it's talking about, specifically,  
<sup>10</sup> formation of a nitroso compound  
<sup>11</sup> which looks like a nitroso  
<sup>12</sup> valsartan. There is a chemical  
<sup>13</sup> formula given in that e-mail which  
<sup>14</sup> is different from that of  
<sup>15</sup> valsartan.

<sup>16</sup> BY MR. SLATER:

<sup>17</sup> Q. Are you aware of the  
<sup>18</sup> language where it says that the NDMA is  
<sup>19</sup> produced by the quenching of the  
<sup>20</sup> valsartan with sodium nitrite? Are you  
<sup>21</sup> aware that the e-mail says that, or do  
<sup>22</sup> you dispute that the e-mail says that?

<sup>23</sup> MS. DAVIDSON: Objection.  
<sup>24</sup> Are you referring to a specific

<sup>1</sup> e-mail, Doctor.

<sup>2</sup> A. Thank you.

<sup>3</sup> And if -- Mr. Slater, if I  
<sup>4</sup> smile, I am not disrespecting you.

<sup>5</sup> Q. I don't mind smiling.

<sup>6</sup> Smiling is great. It's a healthy thing  
<sup>7</sup> to do. It's good for endorphins.

<sup>8</sup> MR. SLATER: I think we're  
<sup>9</sup> up to Exhibit-9 now, right?

<sup>10</sup> - - -  
<sup>11</sup> (Whereupon, Exhibit Afnan-9,  
<sup>12</sup> ZHP00190573-0574, Notice on the  
<sup>13</sup> Results of the Report of the  
<sup>14</sup> Preliminary Investigation on the  
<sup>15</sup> Formation of Unknown Impurities  
<sup>16</sup> Resulting from the Sodium Azide  
<sup>17</sup> Quenching in Crude Irbesartan, was  
<sup>18</sup> marked for identification.)  
<sup>19</sup> - - -

<sup>20</sup> BY MR. SLATER:

<sup>21</sup> Q. So on the screen is  
<sup>22</sup> Exhibit-9.

<sup>23</sup> A. Yes.

<sup>24</sup> Q. That's the e-mail

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1 translation that you saw?

2 A. That is the e-mail

3 translation that I saw.

4 Q. Let's go to the second page,  
5 please.

6 Do you see at the very top  
7 of the second page of the e-mail there's  
8 some language up above some chemistry  
9 formulas? Do you see that?

10 A. Yes.

11 Q. And they're talking in the  
12 first sentence about something that they  
13 saw in irbesartan that they're working on  
14 a manufacturing process for, they're  
15 experimenting with a manufacturing  
16 process, and they're talking about  
17 irbesartan, right?

18 A. Yes.

19 Q. And it says, Through the  
20 secondary mass spectrometry analysis, it  
21 can be inferred that the extra NO  
22 substituent is in the cyclic compound  
23 fragment and it is very likely that it is  
24 an N-NO compound.

1 department carried out the

2 technical improvement by which the  
3 sodium azide quenching takes place  
4 in the unstratified step in the  
5 crude irbesartan process.

6 However, after the  
7 improvement, there is an unknown  
8 impurity of about .544 percent at  
9 26 minutes in the crude  
10 irbesartan, and it is the largest  
11 impurity in the irbesartan crude  
12 product. We investigated, at 26  
13 minutes, unknown impurity that  
14 occurred in the crude irbesartan  
15 after the improvement -- thank  
16 you -- of the sodium azide  
17 quenching process sent by the  
18 technology department.

19 Based on the results of  
20 these two days, currently it can  
21 be confirmed that the impurity is  
22 a nitroso derivative of irbesartan  
23 and its precise molecular weight  
24 of 458.2306, and the signal peak

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1 I'm going to stop there.

2 They're talking about what  
3 they're seeing in the irbesartan, right?

4 MS. DAVIDSON: Objection.

5 THE WITNESS: Can I go to  
6 Page 1 of this e-mail, please?

7 BY MR. SLATER:

8 Q. Sure. Do you need us to do  
9 that for you?

10 MR. SLATER: Go ahead.

11 We'll put on Page 1, let's go.

12 THE WITNESS: I have it  
13 open.

14 According to the results of  
15 our telephone conversation with  
16 the technology department of  
17 Chuannan Plant 1 today, due to the  
18 incomplete quenching of sodium  
19 azide caused by the separate  
20 treatment of irbesartan sodium  
21 azide wastewater, there is a  
22 frequent occurrence of muffled  
23 explosion in the production  
24 process. So the technology

1 of M plus K plus 496.1865 can also  
2 be observed. The matching  
3 molecular formula is C25H27N7O2.  
4 Compared with the molecular  
5 formula of irbesartan, it has an  
6 extra NO but missing one hydrogen  
7 atom. The estimated possible  
8 structural formula is shown as  
9 follows.

10 Okay. Now, he attached to  
11 this e-mail, in Chinese, the  
12 patent. And the patent talks  
13 about Impurity K, Impurity K being  
14 present in that process, not in --  
15 not a nitrosamine in valsartan.

16 So I've gone through this  
17 e-mail several times. And, again,  
18 this is where Jucai Ge's testimony  
19 or -- deposition, not testimony,  
20 becomes very helpful.

21 BY MR. SLATER:

22 Q. Great. All I asked you is  
23 if that first part of the sentence at the  
24 top was referring to irbesartan up to the

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1 semi-colon.  
2 Do you agree that's talking  
3 about what they saw in the irbesartan?  
4 MS. DAVIDSON: Objection.  
5 THE WITNESS: So I would  
6 have to guess. I -- my assumption  
7 is that the whole e-mail is about  
8 irbesartan, from beginning to the  
9 end.  
10 BY MR. SLATER:  
11 Q. The first sentence at the  
12 top of Page 2 says, Through the secondary  
13 mass spectrometry analysis, it can be  
14 inferred that the extra NO substituent is  
15 in the cyclic compound fragment and it is  
16 very likely that it is an N-NO compound.  
17 Do you see what I just read?  
18 A. Yes.  
19 Q. And you just confirmed your  
20 understanding is that has to do with what  
21 they were seeing in irbesartan, right?  
22 MS. DAVIDSON: Objection.  
23 THE WITNESS: I did not.  
24 BY MR. SLATER:

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1 You know that for a fact,  
2 correct?  
3 MS. DAVIDSON: Objection.  
4 THE WITNESS: I do not.  
5 Again, going back to Jucai Ge, Dr.  
6 Lin was situated -- was physically  
7 placed at a different site,  
8 different location. He was  
9 looking -- he was a development  
10 department -- you know, technology  
11 department. He was looking at a  
12 manufacturing process for  
13 irbesartan.  
14 And, actually, specifically  
15 looking at the effluent coming  
16 from the process and looking at  
17 what could be formed and what  
18 could not be formed.  
19 So as he's doing this and he  
20 goes on to say that, you know,  
21 find the patent, which he had  
22 researched and, effectively, this  
23 is a hypothetical e-mail, because  
24 he's responding to the patent.

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1 Q. You literally just said the  
2 entire e-mail is about irbesartan.  
3 Wouldn't that sentence be  
4 included?  
5 A. Well, that is -- again, we  
6 go back to, you know what, it's the  
7 translation of the e-mail, so on and so  
8 forth.  
9 Potentially, yes, it's  
10 referring to irbesartan. Okay.  
11 Q. Now, after the semi-colon  
12 Dr. Lin says, It is similar to the  
13 N-nitroso dimethylamine that occurs in  
14 valsartan when quenched with sodium  
15 nitrite.  
16 Do you see what I just read?  
17 A. Yes.  
18 Q. Forgetting about the e-mail  
19 for a second, as a matter of fact in the  
20 world, as of July 2017, there was NDMA in  
21 valsartan and it was occurring when the  
22 valsartan was quenched with sodium  
23 nitrate. That's when the NDMA was  
24 forming.

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1 And the patent talks about  
2 Impurity K, which is a nitroso  
3 valsartan compound.  
4 BY MR. SLATER:  
5 Q. I'm not asking about the  
6 e-mail right now, this question, okay.  
7 Was there NDMA in the  
8 valsartan manufactured with the zinc  
9 chloride process?  
10 A. That was discovered in June  
11 2018.  
12 Q. So the answer is yes, right?  
13 A. In June 2018, ZHP identified  
14 NDMA in valsartan.  
15 Q. The NDMA was formed at the  
16 point when the sodium azide was quenched  
17 with sodium nitrite; that's when the NDMA  
18 formed, correct?  
19 A. According to FDA analysis,  
20 NDMA was present in the -- NDMA was  
21 present in their second process where  
22 sodium nitrite was formed. It was -- and  
23 then into the zinc chloride process.  
24 That was discovered in June 2018.

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<sup>1</sup> Q. I'm sorry, Doctor, I have to  
<sup>2</sup> ask again, because I have no idea what  
<sup>3</sup> you just said. I just didn't understand  
<sup>4</sup> it.

<sup>5</sup> Doctor, the NDMA formed in  
<sup>6</sup> the zinc chloride process was formed when  
<sup>7</sup> the sodium azide was quenched with sodium  
<sup>8</sup> nitrite; that's when the formation  
<sup>9</sup> occurred, correct?

<sup>10</sup> MS. DAVIDSON: Objection.

<sup>11</sup> THE WITNESS: So as of yet,  
<sup>12</sup> there is no statement by FDA which  
<sup>13</sup> says it formed then. The  
<sup>14</sup> investigation -- deviation  
<sup>15</sup> investigation, which we were  
<sup>16</sup> discussing earlier, specifically  
<sup>17</sup> is looking at multiple pathways of  
<sup>18</sup> formation of NDMA.

<sup>19</sup> BY MR. SLATER:

<sup>20</sup> Q. Do you have an opinion as to  
<sup>21</sup> when the NDMA formed during the zinc  
<sup>22</sup> chloride process? Was it during the  
<sup>23</sup> quenching with sodium nitrite or during  
<sup>24</sup> another part of the process, or do you

<sup>1</sup> assume that there was NDMA in valsartan  
<sup>2</sup> manufactured with the zinc chloride  
<sup>3</sup> process and it occurred and formed when  
<sup>4</sup> the sodium azide was quenched with sodium  
<sup>5</sup> nitrite. I'd also like you to assume  
<sup>6</sup> that, okay?

<sup>7</sup> A. Okay.

<sup>8</sup> Q. Would that change your  
<sup>9</sup> opinion as to when ZHP was aware there  
<sup>10</sup> was NDMA in its valsartan and how it  
<sup>11</sup> formed in July of 2017?

<sup>12</sup> MS. DAVIDSON: Objection.

<sup>13</sup> THE WITNESS: You have two  
<sup>14</sup> assumptions and then you would  
<sup>15</sup> like me to assume a third, based  
<sup>16</sup> on your two assumptions.

<sup>17</sup> So, again, I would like to  
<sup>18</sup> go back to what FDA says, what my  
<sup>19</sup> testimony said, my report states  
<sup>20</sup> is that neither the FDA nor  
<sup>21</sup> industry knew how NDMA was formed,  
<sup>22</sup> neither FDA nor industry had  
<sup>23</sup> methods to test for them.

<sup>24</sup> And so, therefore, if they

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<sup>1</sup> have no opinion?

<sup>2</sup> MS. DAVIDSON: Objection.

<sup>3</sup> THE WITNESS: That I would  
<sup>4</sup> have to defer to a synthetic  
<sup>5</sup> organic chemist. I would suggest  
<sup>6</sup> Dr. Xue.

<sup>7</sup> BY MR. SLATER:

<sup>8</sup> Q. I would like you to assume  
<sup>9</sup> that this e-mail says that what they were  
<sup>10</sup> seeing in the irbesartan was similar to  
<sup>11</sup> the NDMA that occurs in valsartan when  
<sup>12</sup> quenched with sodium nitrite. I'd like  
<sup>13</sup> you to assume that that's what the e-mail  
<sup>14</sup> says, okay?

<sup>15</sup> Do you understand that I'm  
<sup>16</sup> asking you to assume that?

<sup>17</sup> A. So you want me to go into  
<sup>18</sup> hypothetical, okay.

<sup>19</sup> Q. I do. You may not know  
<sup>20</sup> this, but we're allowed to ask  
<sup>21</sup> hypothetical questions of expert  
<sup>22</sup> witnesses.

<sup>23</sup> A. I appreciate that.

<sup>24</sup> Q. And I'd also like you to

<sup>1</sup> didn't know how to test for it and  
<sup>2</sup> if they didn't know it was there,  
<sup>3</sup> then the question is that -- the  
<sup>4</sup> engagement between you and I is  
<sup>5</sup> purely theoretical, and not even  
<sup>6</sup> theoretical, it's hypothetical.

<sup>7</sup> So, you know, at the time of  
<sup>8</sup> 2017, ZHP did not know that NDMA  
<sup>9</sup> was present in its valsartan.

<sup>10</sup> BY MR. SLATER:

<sup>11</sup> Q. Can you answer my question,  
<sup>12</sup> please?

<sup>13</sup> MS. DAVIDSON: Objection.

<sup>14</sup> THE WITNESS: Please ask it  
<sup>15</sup> again.

<sup>16</sup> Hypothetical 1 was what,  
<sup>17</sup> that there is --

<sup>18</sup> BY MR. SLATER:

<sup>19</sup> Q. I'll ask the question  
<sup>20</sup> differently for you.

<sup>21</sup> A. Thank you.

<sup>22</sup> Q. I already have your one  
<sup>23</sup> answer, so we have that for the record in  
<sup>24</sup> the transcript as your sworn testimony.

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1 Now I'll ask a different  
2 question in a different way.

3 If the e-mail says that  
4 there was NDMA in valsartan and it occurs  
5 when it's quenched with sodium nitrite,  
6 that would be an accurate statement,  
7 correct?

8 MS. DAVIDSON: Objection.

9 THE WITNESS: If the e-mail  
10 said NDMA was present, yes, but  
11 the e-mail does not say that.

12 BY MR. SLATER:

13 Q. And if that was a correct  
14 statement -- well, rephrase.

15 And if the e-mail says that  
16 there was NDMA in valsartan and it  
17 occurred when the valsartan was quenched  
18 with sodium nitrite, not only would that  
19 be a true statement, but it would also  
20 prove that at least some people in ZHP  
21 were aware of the presence of the NDMA  
22 and how it was forming, right?

23 MS. DAVIDSON: Objection.

24 THE WITNESS: ZHP did not

1 required them to immediately notify their  
2 customers and the FDA and cease  
3 manufacture with that process until they  
4 got further guidance, correct?

5 MS. DAVIDSON: Objection.

6 THE WITNESS: ZHP did  
7 exactly that in June 2018.

8 BY MR. SLATER:

9 Q. And if they knew that in  
10 July of 2017, they would have been  
11 required to do it in July of 2017 and not  
12 wait until June of 2018, right?

13 A. Whenever they would have  
14 become aware of it, they would have had  
15 to act. But that was not the case, they  
16 did not know in June 2017.

17 Q. Well, you actually don't  
18 know when they knew; you're just deciding  
19 which witnesses to believe and which  
20 translations of the document to believe,  
21 but you don't know at all what happened,  
22 right?

23 MS. DAVIDSON: Objection.

24 THE WITNESS: Respectfully,

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1 know -- again, you know, ZHP did  
2 not know.

3 Dr. Lin says that's not what  
4 he said in the e-mail. Jucai Ge  
5 says that's not what it says in  
6 the e-mail. So, you know, it's  
7 purely hypothetical to go down  
8 this path that if this happened  
9 and that happened, then this other  
10 thing would have happened.

11 As your statements, your  
12 conclusion, based on your  
13 theoretical statements, are  
14 connected. But that's not the  
15 case here. I really need to make  
16 sure my testimony is accurate, as  
17 accurate as it can be.

18 BY MR. SLATER:

19 Q. If ZHP knew that there was  
20 NDMA in valsartan and knew that it was  
21 forming during the quenching of the  
22 valsartan during the manufacturing  
23 process with sodium nitrite, if they knew  
24 that, good manufacturing practices

1 incorrect. I -- you know, seven  
2 years at FDA told me to look for  
3 evidence, look for evidence, look  
4 for evidence.

5 The evidence is there when  
6 they received an e-mail, or a  
7 communication, from Novartis  
8 saying, what is that peak which is  
9 there, send us data. They did  
10 send data. They sent GC FID data.  
11 They also sent GCMS data which was  
12 not alluding, you know, the  
13 unknown peak.

14 BY MR. SLATER:

15 Q. Did you -- I'm sorry, I  
16 didn't realize you were still talking.  
17 Go ahead.

18 A. So Novartis actually told  
19 them that the chances are that using your  
20 method, it will dilute at a different  
21 time than ours. FDA didn't know either.

22 So FDA, who had reviewed the  
23 ANDAs related to this API, would have  
24 known, would have actually assessed

<p style="text-align: right;">Page 238</p> <p><sup>1</sup> whether NDMA would have been formed or <sup>2</sup> not.</p> <p><sup>3</sup> So ZHP didn't know until <sup>4</sup> June 2018.</p> <p><sup>5</sup> Q. You just mentioned the FDA <sup>6</sup> review of the ANDAs.</p> <p><sup>7</sup> You just referred to that, <sup>8</sup> right?</p> <p><sup>9</sup> A. Yes.</p> <p><sup>10</sup> Q. When the FDA did whatever <sup>11</sup> review it did of the ANDAs that were <sup>12</sup> filed, is it your testimony that the FDA <sup>13</sup> would, at that point, have done a <sup>14</sup> cGMP-compliant risk assessment of the <sup>15</sup> entire manufacturing process?</p> <p><sup>16</sup> MS. DAVIDSON: Objection.</p> <p><sup>17</sup> THE WITNESS: So there are <sup>18</sup> parallel activities for an <sup>19</sup> approval process going on. One <sup>20</sup> activity is what's going on at the <sup>21</sup> API facility. And that API <sup>22</sup> facility was also inspected in, I <sup>23</sup> think, 2011 and then in 2016 by <sup>24</sup> EDQM, who accepted the facility</p>	<p style="text-align: right;">Page 240</p> <p><sup>1</sup> BY MR. SLATER:</p> <p><sup>2</sup> Q. Or I can ask it again.</p> <p><sup>3</sup> Do you want me to ask you <sup>4</sup> again, Doctor?</p> <p><sup>5</sup> Because I don't really <sup>6</sup> understand what you just said. So I'm <sup>7</sup> going to try to ask a question that's <sup>8</sup> specific and hope that I can get a <sup>9</sup> specific answer. That's my hope.</p> <p><sup>10</sup> When the FDA reviewed the <sup>11</sup> ANDAs that were submitted with regard -- <sup>12</sup> which then incorporated, by reference, <sup>13</sup> the DMFs for the TEA with sodium nitrite <sup>14</sup> quenching and the zinc chloride <sup>15</sup> processes, did the FDA perform a <sup>16</sup> cGMP-compliant risk assessment of each of <sup>17</sup> those manufacturing processes?</p> <p><sup>18</sup> A. I did respond.</p> <p><sup>19</sup> Q. It's a yes-or-no question.</p> <p><sup>20</sup> Can you just tell me if the <sup>21</sup> review by the FDA is to the level of a <sup>22</sup> cGMP-compliant risk assessment?</p> <p><sup>23</sup> A. With all due respect, sir, <sup>24</sup> your question is wrong.</p>
<p style="text-align: right;">Page 239</p> <p><sup>1</sup> and gave them a GMP certificate.</p> <p><sup>2</sup> FDA had the DMF, which -- <sup>3</sup> which the process, there's a <sup>4</sup> chlorine process had been filed <sup>5</sup> through as an amendment. That was <sup>6</sup> also there.</p> <p><sup>7</sup> The ANDA process would have <sup>8</sup> looked at, effectively, the tests <sup>9</sup> for the API. It would have looked <sup>10</sup> for the process of making the drug <sup>11</sup> substance, and -- the process, as <sup>12</sup> well as the release criteria for <sup>13</sup> the raw substance. And they would <sup>14</sup> have looked at whether the <sup>15</sup> chemistry recorded in the sections <sup>16</sup> of the Model 3 would be accurate, <sup>17</sup> correct or not.</p> <p><sup>18</sup> And that would have then <sup>19</sup> been verified through either a GMP <sup>20</sup> inspection or a PAI inspection.</p> <p><sup>21</sup> BY MR. SLATER:</p> <p><sup>22</sup> Q. Could you answer my <sup>23</sup> question, please?</p> <p><sup>24</sup> MS. DAVIDSON: Objection.</p>	<p style="text-align: right;">Page 241</p> <p><sup>1</sup> They review an ANDA <sup>2</sup> application. It's not a GMP activity. <sup>3</sup> It's managed through other sections of <sup>4</sup> the CFR. So FDA would have looked at the <sup>5</sup> sections of the common technical dossier <sup>6</sup> that would have been provided. They <sup>7</sup> would have also looked at the GMP status <sup>8</sup> of the facility for approval of the ANDA.</p> <p><sup>9</sup> Q. Looking at the e-mail of <sup>10</sup> July 27, 2017, the second paragraph after <sup>11</sup> the chemistry diagrams says, If it is <sup>12</sup> confirmed as the above-speculated <sup>13</sup> structure, then its toxicity will be very <sup>14</sup> strong and there will be an extremely <sup>15</sup> high GMP risk. This is a common problem <sup>16</sup> in the production and synthesis of sartan <sup>17</sup> APIs. It is recommended to improve other <sup>18</sup> quenching processes (such as NACIO) along <sup>19</sup> with the optimization of the valsartan <sup>20</sup> sodium azide quenching process.</p> <p><sup>21</sup> Do you see that?</p> <p><sup>22</sup> A. I see that.</p> <p><sup>23</sup> Q. So, first of all, where he <sup>24</sup> says, This is a common problem with the</p>

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<sup>1</sup> production and synthesis of sartan APIs,  
<sup>2</sup> you understand that ZHP manufactured  
<sup>3</sup> other sartans, including irbesartan?

<sup>4</sup> A. Yes.

<sup>5</sup> Q. If ZHP was aware that the  
<sup>6</sup> quenching with sodium nitrite causing  
<sup>7</sup> nitrosamines was a common problem in the  
<sup>8</sup> production and synthesis of sartan APIs,  
<sup>9</sup> they would have been duty bound to notify  
<sup>10</sup> the FDA and their customers with regard  
<sup>11</sup> to all of their sartans, correct?

<sup>12</sup> If that's what they knew,  
<sup>13</sup> they would have been required to notify  
<sup>14</sup> the FDA and their customers, right?

<sup>15</sup> A. As the e-mail says, it says  
<sup>16</sup> if it is confirmed. And by the way,  
<sup>17</sup> that's NACLO, sodium hydrochloride.

<sup>18</sup> So it says, If it is  
<sup>19</sup> confirmed as the above speculated  
<sup>20</sup> structure, then its toxicity will be  
<sup>21</sup> strong. Okay.

<sup>22</sup> Q. He then says, It is  
<sup>23</sup> recommended to improve other quenching  
<sup>24</sup> processes along with the optimization of

<sup>1</sup> impurities.

<sup>2</sup> Which, actually, as per the  
<sup>3</sup> attached, is a -- is a nitroso valsartan.  
<sup>4</sup> You know, the nitroso compounds are many  
<sup>5</sup> and plenty. And, therefore, that  
<sup>6</sup> compound that he's referring to, if you  
<sup>7</sup> look at the patent, is actually Impurity  
<sup>8</sup> K.

<sup>9</sup> Q. Do you see where this says,  
<sup>10</sup> At the same time they -- meaning this  
<sup>11</sup> other company, Zhejiang Second Pharma  
<sup>12</sup> Company -- used ZHP's crude valsartan in  
<sup>13</sup> their LC-MS test and detected this  
<sup>14</sup> impurity.

<sup>15</sup> And the impurity that was  
<sup>16</sup> referred to above in the valsartan was  
<sup>17</sup> NDMA, correct?

<sup>18</sup> A. Hold on. I lost you. Okay.  
<sup>19</sup> Allow me.

<sup>20</sup> So, okay. What was your  
<sup>21</sup> question, please?

<sup>22</sup> Q. This states that this other  
<sup>23</sup> pharmaceutical company used ZHP's crude  
<sup>24</sup> valsartan in their LC-MS test and

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<sup>1</sup> the valsartan sodium azide quenching  
<sup>2</sup> process.

<sup>3</sup> If that's correct, that he  
<sup>4</sup> was recommending, based on everything he  
<sup>5</sup> talked about, optimizing the valsartan  
<sup>6</sup> sodium azide quenching process, based on  
<sup>7</sup> having stated above that the NDMA was  
<sup>8</sup> formed during the sodium nitrite  
<sup>9</sup> quenching of the sodium azide, that would  
<sup>10</sup> be something that ZHP would have been  
<sup>11</sup> required to notify the FDA and their  
<sup>12</sup> customers of immediately, right?

<sup>13</sup> A. If that was the case, they  
<sup>14</sup> would have had to inform FDA and  
<sup>15</sup> customers immediately. That was not the  
<sup>16</sup> case.

<sup>17</sup> If I may be allowed to read  
<sup>18</sup> the next line of the next paragraph. I  
<sup>19</sup> have also attached a patent of a 2013  
<sup>20</sup> sodium azide sodium hyperchloride  
<sup>21</sup> quenching method by Zhejiang Second  
<sup>22</sup> Pharma Company Limited. They proposed  
<sup>23</sup> that the use of sodium azide quenching  
<sup>24</sup> will result in the formation of N-NO

<sup>1</sup> detected this impurity.

<sup>2</sup> The impurity that was  
<sup>3</sup> identified up above in the valsartan was  
<sup>4</sup> listed as NDMA, correct?

<sup>5</sup> A. Can you point me to where it  
<sup>6</sup> says this is NDMA?

<sup>7</sup> Q. Sure.

<sup>8</sup> MR. SLATER: Scroll to the  
<sup>9</sup> top, please.

<sup>10</sup> THE WITNESS: Okay. This is  
<sup>11</sup> similar, similar, to  
<sup>12</sup> N-nitrosamines. This is similar.

<sup>13</sup> BY MR. SLATER:

<sup>14</sup> Q. You don't have to read the  
<sup>15</sup> rest of the sentence, Doctor. With all  
<sup>16</sup> due respect, it says that what they saw  
<sup>17</sup> in the irbesartan was similar to the NDMA  
<sup>18</sup> that occurs in valsartan when quenched  
<sup>19</sup> with sodium nitrite.

<sup>20</sup> That's what the document  
<sup>21</sup> says, right?

<sup>22</sup> MS. DAVIDSON: Objection.

<sup>23</sup> That's what the translation says.

<sup>24</sup> THE WITNESS: Which, again,

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1 if I follow what I said earlier,  
2 if I look at both Professor Xue  
3 and if I look at Jucai Ge, who  
4 spoke to Dr. Lin in detail and  
5 asked the questions, Dr. Lin says,  
6 I never made that statement. That  
7 was not my intent.

8 So as we go through to the  
9 second question, or the last  
10 paragraph, yes, the statement  
11 which says, At the same time they  
12 used ZHP's crude valsartan.

13 So this e-mail was about  
14 Impurity K. This is about  
15 Impurity K, which is a nitroso  
16 valsartan. It's a valsartan  
17 molecule with an N-O attached to  
18 it.

19 BY MR. SLATER:

20 Q. Now you think the whole  
21 e-mail is about Impurity K? It's not  
22 about irbesartan anymore?

23 MS. DAVIDSON: Objection.

24 BY MR. SLATER:

1 Adam. But you're arguing with the  
2 witness. And my job today is to  
3 make sure that this deposition  
4 proceeds in an appropriate manner.

5 The way you're talking to  
6 the witness is rude. So I'm just  
7 asking you not to.

8 MR. SLATER: I don't think  
9 I'm being rude at all. There's an  
10 audiotape of this transcript -- of  
11 this deposition, the video has an  
12 audio. So anybody that needs to  
13 look at it, I stand behind  
14 everything I've done today.

15 I have one of the most  
16 nonresponsive witnesses I've ever  
17 deposed in my life. I feel like  
18 the deposition has been obstructed  
19 to a great extent, and I'm doing  
20 the best I can.

21 I'm not raising my voice.  
22 And I'm not yelling. And I think  
23 that my request to not lead the  
24 witness with speaking objections

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1 Q. I'm just asking.

2 Before you said the whole  
3 e-mail was about irbesartan, now it's  
4 about Impurity K?

5 MS. DAVIDSON: Wait a  
6 minute. That's really  
7 mischaracterizing his testimony  
8 and --

9 MR. SLATER: Without you  
10 giving him what to say. You  
11 objected. He can answer.

12 MS. DAVIDSON: I'm not  
13 telling --

14 MR. SLATER: He doesn't need  
15 to take signal from you. The last  
16 one he followed your objection and  
17 followed it and said exactly what  
18 you said. Let's try not to do  
19 that, please.

20 MS. DAVIDSON: That is  
21 literally the pot calling --

22 MR. SLATER: I don't want to  
23 argue with you. I really don't.

24 MS. DAVIDSON: I understand,

1 is reasonable.

2 MS. DAVIDSON: I did not  
3 lead the witness in any way, and  
4 you know that. I was asking you  
5 to please be polite, not badger  
6 him, and just simply ask questions  
7 and answers, which would make the  
8 deposition go more quickly.

9 You're concerned about  
10 eating up time, but you're eating  
11 up time berating the witness.

12 BY MR. SLATER:

13 Q. Show me where it says  
14 Impurity K in the e-mail. I just -- I  
15 might have missed that.

16 A. Impurity K is in the patent,  
17 which was attached to the e-mail.

18 MR. SLATER: We can take  
19 that down.

20 I just need to know if you  
21 guys are going to say you need a  
22 break again, because I'm going to  
23 go into something else.

24 If you need a break, you can

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1 do it now. Otherwise I'd like to  
 2 start and not stop in three  
 3 minutes.

4 MS. DAVIDSON: I've been  
 5 trying to take a break about every  
 6 hour, and I believe we came back  
 7 at 2:05. So I was not going to  
 8 ask for another break for 15  
 9 minutes.

10 Unless Dr. Afnan needs one  
 11 now. He's the one who should be  
 12 the guide of it.

13 THE WITNESS: Let's go for  
 14 another ten minutes, please.

15 MR. SLATER: I'm just  
 16 putting up the next exhibit.  
 17 - - -

18 (Whereupon, Exhibit  
 19 Afnan-10, No Bates, FDA Statement  
 20 on the FDA's Ongoing Investigation  
 21 Into Valsartan and ARB Class  
 22 Impurities and the Agency's Steps  
 23 to Address the Root Causes of the  
 24 Safety Issues, was marked for

1 page of this e-mail -- rephrase.

2 Looking now at the second  
 3 page of this statement, there's a  
 4 paragraph that starts, Since then, the  
 5 FDA and additional manufacturers of other  
 6 ARB medicines have identified more cases  
 7 of NDMA impurities as well as NDEA  
 8 impurities.

9 Do you see that?

10 A. Yes.

11 Q. Looking now at the paragraph  
 12 that starts with, Since then, the second  
 13 sentence says, We've placed a ZHP  
 14 facility on import alert to stop all of  
 15 its API and finished drugs made using  
 16 ZHP's API from legally entering the  
 17 United States. We also issued them a  
 18 warning letter outlining several  
 19 manufacturing violations, including  
 20 impurity control, change control and  
 21 cross-contamination from one  
 22 manufacturing process line to another.

23 Do you see what I just read?

24 A. Yes.

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1 identification.)  
 2 - - -

3 BY MR. SLATER:

4 Q. On the screen is what we  
 5 have marked as Exhibit -- I think  
 6 we're -- on the screen is Exhibit-10,  
 7 which is an FDA statement dated January  
 8 25, 2019.

9 Do you see that?

10 A. Yes.

11 Q. Is this something you relied  
 12 on in forming your opinions in this case?

13 A. It is quoted in my -- in my  
 14 testimony, so yes.

15 MR. SLATER: Let's go to the  
 16 second page, third paragraph.  
 17 Blow it up a little bit.

18 I'm just going to go -- the  
 19 paragraph that starts, Since then.  
 20 There we go.

21 BY MR. SLATER:

22 Q. I'm looking at the -- let me  
 23 restart.

24 Looking now at the second

1 Q. So in this FDA statement  
 2 that you relied on, the FDA makes clear  
 3 that they issued a warning letter to ZHP,  
 4 correct?

5 A. Correct.

6 Q. They made clear that the  
 7 warning letter outlined several  
 8 manufacturing violations, correct?

9 MS. DAVIDSON: Objection.

10 BY MR. SLATER:

11 Q. Correct?

12 A. That's what the warning  
 13 letter says.

14 Q. And those violations are  
 15 cGMP violations identified in the warning  
 16 letter, correct?

17 A. Okay. Yes.

18 Q. They then list, in general  
 19 fashion, the nature of those cGMP  
 20 manufacturing violations as including  
 21 impurity control, change control and  
 22 cross-contamination from one  
 23 manufacturing process line to another.

24 That's what it says, right?

<p>1 A. Yes.</p> <p>2 Q. So in this statement that</p> <p>3 you relied on, the FDA made clear, in</p> <p>4 January of 2019, that they issued an</p> <p>5 import alert against ZHP and issued them</p> <p>6 a warning letter identifying several</p> <p>7 manufacturing violations of cGMP.</p> <p>8 That's in the letter, right?</p> <p>9 That's in the statement, right?</p> <p>10 MS. DAVIDSON: Objection.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. Correct?</p> <p>13 A. That's what the letter says.</p> <p>14 Q. If you go to the last</p> <p>15 sentence of this paragraph, it says,</p> <p>16 Nonetheless, our inspections did reveal</p> <p>17 systemic problems of supervision that</p> <p>18 could have created the conditions for</p> <p>19 quality issues to arise.</p> <p>20 That's what the letter</p> <p>21 says -- that's what the statement says,</p> <p>22 again, with regard to their inspections</p> <p>23 of ZHP, correct?</p> <p>24 A. That's what it says in the</p>	<p>Page 254</p> <p>1 grounds to do this.</p> <p>2 Now, in this particular</p> <p>3 case, FDA is doing several things.</p> <p>4 Number one, FDA is</p> <p>5 effectively holding ZHP on the hook to</p> <p>6 complete its investigation. Their</p> <p>7 warning letter is issued in November of</p> <p>8 2018. The inspection was from 27th of</p> <p>9 July to 3rd of August. They -- ZHP</p> <p>10 informed FDA, in June, of presence of</p> <p>11 NDMA and at the same time informed FDA</p> <p>12 that it had stopped manufacture of</p> <p>13 valsartan, it had stopped shipping</p> <p>14 valsartan and it had informed its clients</p> <p>15 to stop using the API. They have done it</p> <p>16 twice.</p> <p>17 So, effectively, the warning</p> <p>18 letter is coming pretty late in the day.</p> <p>19 And that's because FDA is still waiting</p> <p>20 for the investigation to complete and for</p> <p>21 ZHP to give the information to them.</p> <p>22 When -- the evidence of this</p> <p>23 is, when ZHP responded, ZHP gave an</p> <p>24 immediate response and then gave a</p>
<p>1 letter, yes.</p> <p>2 MR. SLATER: We can take</p> <p>3 that one down.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. With regard to the import of</p> <p>6 the warning letter, the warning letter is</p> <p>7 a serious document, correct?</p> <p>8 MS. DAVIDSON: Objection.</p> <p>9 THE WITNESS: The warning</p> <p>10 letter is informal and advisory.</p> <p>11 That's what the FDA says. FDA</p> <p>12 doesn't consider warning letters</p> <p>13 as final agency action. That's</p> <p>14 what the FDA says.</p> <p>15 BY MR. SLATER:</p> <p>16 Q. The warning letters are</p> <p>17 issued only for violations of regulatory</p> <p>18 significance; that's the position of the</p> <p>19 FDA, right?</p> <p>20 A. There is a sequence to the</p> <p>21 issuance of warning letters. The</p> <p>22 sequence is that there is an inspection,</p> <p>23 there is a response from the firm, then a</p> <p>24 warning letter is issued if there is</p>	<p>Page 255</p> <p>1 detailed response, FDA came back with</p> <p>2 some additional questions and very</p> <p>3 friendly tone asking for, can you speed</p> <p>4 up some of the questions?</p> <p>5 So the warning letter is not</p> <p>6 a, you know, this is the end of the day.</p> <p>7 The warning letter is to engage in a</p> <p>8 dialogue with the agency to get to the</p> <p>9 root cause of the issue. That's why</p> <p>10 warning letters are issued.</p> <p>11 And, again, the warning</p> <p>12 letter, according to the regulatory</p> <p>13 operations manual, is not -- is informal</p> <p>14 and advisory, and it's not considered</p> <p>15 warning letters -- you know, they aren't</p> <p>16 considered to be final agency action.</p> <p>17 Q. The FDA never, ever came out</p> <p>18 and said that the violations identified</p> <p>19 in the warning letter did not exist and</p> <p>20 did not occur? The FDA never said that,</p> <p>21 right?</p> <p>22 A. Well, FDA closed the warning</p> <p>23 letter sometime later, which means it</p> <p>24 accepted it.</p>

1 ZHP had already challenged  
 2 some of the observations, and ZHP  
 3 continued to engage the FDA in its  
 4 response to the warning letter, addressed  
 5 those issues.

6 Q. What the FDA did is, they  
 7 said, now that we've identified these  
 8 serious systemic problems and we've given  
 9 you the warning letter, fix them; here is  
 10 the violations and now you have to fix it  
 11 and we're reserving the right to take  
 12 final enforcement action if we want to.

13 And then three years later,  
 14 or two years later, they finally said to  
 15 ZHP, okay, on a going-forward basis, you  
 16 finally fixed these problems, we're going  
 17 to finally remove you from the import  
 18 alert.

19 That's what actually  
 20 occurred, right?

21 A. No.

22 MS. DAVIDSON: Objection.

23 THE WITNESS: So the import  
 24 alert is actually -- you know, the

1 So when you sell a batch of APIs,  
 2 the API can be used continuously  
 3 until they run out.

4 What FDA wanted to do, very  
 5 specifically, was to make sure  
 6 that the drug product  
 7 manufacturers, who ZHP had no  
 8 control over, would not ship those  
 9 products to the U.S.

10 The fastest, the easiest and  
 11 the most convenient solution is an  
 12 import alert.

13 BY MR. SLATER:

14 Q. When I read your report, I  
 15 thought you said something to the effect  
 16 of once the import alert was lifted, if  
 17 ZHP wanted to, it could start re -- it  
 18 could start selling its valsartan again,  
 19 the valsartan manufactured with the zinc  
 20 chloride process.

21 Did you mean to say that in  
 22 your report, or did I misread your  
 23 report?

24 MS. DAVIDSON: Objection.

1 import alert has a very specific  
 2 purpose. And I'm looking for a  
 3 text out of my report which I will  
 4 come to.

5 The import alert is there to  
 6 prevent potentially violative  
 7 product getting into the market.  
 8 And it's also, according to FDA,  
 9 is to free up its resources so  
 10 that it can examine other  
 11 shipments.

12 Now, it also -- FDA also  
 13 wants a uniform coverage across  
 14 the United States, across the  
 15 country, and also to put the  
 16 responsibility back on the firm.

17 So the issue with this is  
 18 that the import alert, which was  
 19 initiated, I think, in September,  
 20 the import alert was put in place  
 21 on the same day FDA asked for a  
 22 list of clients of ZHP.

23 APIs, when they are sold,  
 24 there is no expiry date for API.

1 THE WITNESS: So the DMF has  
 2 not been changed. The DMF is  
 3 there and it's acting. If --

4 BY MR. SLATER:

5 Q. So in your opinion, they  
 6 can --

7 MS. DAVIDSON: Whoa. He was  
 8 in the middle of talking, Adam.

9 THE WITNESS: So if I go  
 10 back and look at also on the  
 11 subject of, okay, so what happened  
 12 and what did they do, Point 98 in  
 13 my statement says, In the EIR --  
 14 this is the 2018 EIR which  
 15 resulted in a response and warning  
 16 letter and an import alert -- they  
 17 investigated, documented that he  
 18 reviewed the stability protocol  
 19 for valsartan implemented in 2012  
 20 and everything was good.

21 And he says, And noted that  
 22 all data reported within  
 23 specification, and results were  
 24 similar across the U.S. and

<p>1 non-U.S. market.</p> <p>2 99. The EIR, the 2018 EIR,</p> <p>3 noted that ZHP has an established</p> <p>4 quality unit, consists of quality</p> <p>5 assurance department and quality</p> <p>6 control lab. It further noted</p> <p>7 that the firm has established</p> <p>8 written procedures for the quality</p> <p>9 unit covering supplier</p> <p>10 qualification, training, batch</p> <p>11 release validation, calibration,</p> <p>12 investigation, including deviation</p> <p>13 and product recalls, stability</p> <p>14 studies and complaints.</p> <p>15 So they investigated, as</p> <p>16 documented, that the quality unit</p> <p>17 is functioning well.</p> <p>18 100. The inspector observed</p> <p>19 employees' practices, reviewed</p> <p>20 documents and conducted</p> <p>21 personal -- personal interviews</p> <p>22 with various staff members to</p> <p>23 assess whether the firm's quality</p> <p>24 system is designed to achieve</p>	<p>1 again in light of the events and</p> <p>2 in consideration of what was going</p> <p>3 on. ZHP informed FDA that it had</p> <p>4 NDMA in its valsartan. FDA came</p> <p>5 for an inspection, gave them a set</p> <p>6 of observations, and then an</p> <p>7 import alert, which effectively</p> <p>8 was to prevent material from all</p> <p>9 these drug product manufacturers</p> <p>10 coming into the U.S., as well as</p> <p>11 keeping them on hook.</p> <p>12 Now, the DMF is still</p> <p>13 active. The DMF with zinc</p> <p>14 chloride is still active, because</p> <p>15 the quality system is functioning</p> <p>16 properly.</p> <p>17 BY MR. SLATER:</p> <p>18 Q. Is the import of you saying,</p> <p>19 after that answer at the end, that DMF,</p> <p>20 for the zinc chloride process, is still</p> <p>21 in effect, that if ZHP wants to, it can</p> <p>22 manufacture and sell valsartan</p> <p>23 manufactured with the zinc chloride</p> <p>24 process?</p>
<p>1 sufficient control over the</p> <p>2 facility and commercial</p> <p>3 manufacturing questions.</p> <p>4 Through these activities,</p> <p>5 she observed the quality unit is</p> <p>6 involved in activities, including</p> <p>7 but not limited to, review of</p> <p>8 manufacturing documents and</p> <p>9 approval, product prior to release</p> <p>10 qualification and validation</p> <p>11 activities, deviations and</p> <p>12 investigation and change control</p> <p>13 activities.</p> <p>14 A lot of what resulted in</p> <p>15 the warning letter, and a lot of</p> <p>16 what went on during the</p> <p>17 inspection, was ongoing</p> <p>18 investigation.</p> <p>19 So looking at 98, 99 and</p> <p>20 100, the quality unit of ZHP was</p> <p>21 on par. It was functioning</p> <p>22 according to the GMPs.</p> <p>23 So the import alert and the</p> <p>24 warning letter have to be taken</p>	<p>1 MS. DAVIDSON: Objection.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. Yes or no?</p> <p>4 MS. DAVIDSON: Objection.</p> <p>5 Enough with the yes-or-no</p> <p>6 follow-ups to every question.</p> <p>7 THE WITNESS: Sorry. I will</p> <p>8 not give you a yes-or-no answer.</p> <p>9 I'll tell you what is there.</p> <p>10 ZHP stopped manufacturing</p> <p>11 using the process that was</p> <p>12 resulting in NDMA in June of 2018.</p> <p>13 They immediately stopped.</p> <p>14 They started looking at</p> <p>15 their process. They put it right.</p> <p>16 And as I said, the DMF is</p> <p>17 still active. Are they selling or</p> <p>18 not? I have no information about</p> <p>19 that. I know that the DMF is</p> <p>20 active.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. Is ZHP permitted, if it</p> <p>23 wants to, today, to manufacture and sell</p> <p>24 in the United States valsartan</p>

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<sup>1</sup> manufactured with the zinc chloride  
<sup>2</sup> process; yes or no?

<sup>3</sup> MS. DAVIDSON: Objection.

<sup>4</sup> THE WITNESS: ZHP is allowed  
<sup>5</sup> to sell valsartan against the DMF  
<sup>6</sup> which is active.

<sup>7</sup> MR. SLATER: Thank you. We  
<sup>8</sup> can take a break. We can go off  
<sup>9</sup> the record.

<sup>10</sup> THE WITNESS: Thank you.

<sup>11</sup> VIDEO TECHNICIAN: We're off  
<sup>12</sup> the record at 3:10 p.m.

- - -

<sup>14</sup> (Whereupon, a brief recess  
<sup>15</sup> was taken.)

- - -

<sup>17</sup> VIDEO TECHNICIAN: We're  
<sup>18</sup> back on the record at 3:36 p.m.

<sup>19</sup> BY MR. SLATER:

<sup>20</sup> Q. I'm showing you what was  
<sup>21</sup> attached as Exhibit B to your initial  
<sup>22</sup> report of December 23, 2022, the list of  
<sup>23</sup> materials reviewed and considered.

<sup>24</sup> A. Yes.

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<sup>1</sup> deposition of David Chesney?

<sup>2</sup> A. Yes.

<sup>3</sup> Q. Did you read those  
<sup>4</sup> documents?

<sup>5</sup> A. Yes.

<sup>6</sup> Q. Do you know Mr. Chesney?

<sup>7</sup> A. I know of Mr. Chesney. I  
<sup>8</sup> don't know him as an acquaintance or a  
<sup>9</sup> friend.

<sup>10</sup> Q. Did you take into account  
<sup>11</sup> the opinions that he offered during his  
<sup>12</sup> deposition?

<sup>13</sup> MS. DAVIDSON: Objection.

<sup>14</sup> THE WITNESS: Did I take  
<sup>15</sup> into account -- I read his  
<sup>16</sup> deposition.

<sup>17</sup> BY MR. SLATER:

<sup>18</sup> Q. Were any of the things that  
<sup>19</sup> David Chesney said in his deposition of  
<sup>20</sup> any significance to you in forming your  
<sup>21</sup> opinions in this case?

<sup>22</sup> A. So were they of  
<sup>23</sup> significance? Again, we've been there  
<sup>24</sup> before. And I said, what do you mean by

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<sup>1</sup> Q. Did you read all those  
<sup>2</sup> documents?

<sup>3</sup> A. I -- if it's there, I read  
<sup>4</sup> it.

<sup>5</sup> Q. And it's your testimony if  
<sup>6</sup> it is there you read it cover to cover,  
<sup>7</sup> every one of the documents?

<sup>8</sup> A. So some cover to cover, some  
<sup>9</sup> several times, some I gleaned through.

<sup>10</sup> Q. Did you read all the  
<sup>11</sup> deposition transcripts listed there  
<sup>12</sup> completely?

<sup>13</sup> A. I read the deposition  
<sup>14</sup> transcripts starting when I started on  
<sup>15</sup> this project, yes.

<sup>16</sup> Q. You read every single one of  
<sup>17</sup> those deposition transcripts cover to  
<sup>18</sup> cover?

<sup>19</sup> MS. DAVIDSON: Objection.

<sup>20</sup> THE WITNESS: So I have read  
<sup>21</sup> those depositions, yes.

<sup>22</sup> BY MR. SLATER:

<sup>23</sup> Q. One of the things I saw you  
<sup>24</sup> were provided was the expert report and

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<sup>1</sup> "significance," and you said, did I read  
<sup>2</sup> it?

<sup>3</sup> So my answer is, based on  
<sup>4</sup> that definition, yes, I read it. Did  
<sup>5</sup> he -- did I take it into account? Yes, I  
<sup>6</sup> did.

<sup>7</sup> Q. Was there anything that  
<sup>8</sup> Mr. Chesney testified to where you looked  
<sup>9</sup> at it and said, you know, that's  
<sup>10</sup> something that's important, I'm going to  
<sup>11</sup> rely on that for my opinion? Anything  
<sup>12</sup> you can think of?

<sup>13</sup> A. I don't recall.

<sup>14</sup> MR. SLATER: Let's put up  
<sup>15</sup> the supplemental list, please. I  
<sup>16</sup> guess that would be a new exhibit,  
<sup>17</sup> 12?

- - -

<sup>19</sup> (Whereupon, Exhibit  
<sup>20</sup> Afnan-11, No Bates, Exhibit  
<sup>21</sup> B-Materials Reviewed and  
<sup>22</sup> Considered (Amended and  
<sup>23</sup> Supplemental), was marked for  
<sup>24</sup> identification.)

	Page 270		Page 272
1	- - -	1	Do you understand the
2	BY MR. SLATER:	2	hypothetical I'm putting you in?
3	Q. So now we marked as	3	MS. DAVIDSON: I'm sorry, my
4	Exhibit-11 your amended and supplemental	4	computer froze, and I missed the
5	list of materials reviewed and	5	hypothetical.
6	considered.	6	Can you read it back?
7	Have you seen that document?	7	MR. SLATER: I'll do it.
8	A. Yes.	8	BY MR. SLATER:
9	Q. Does this list everything	9	Q. I want you to assume that
10	that you have seen, as of now, relative	10	Dr. Hecht and Dr. Najafi are correct
11	to this case?	11	about what ZHP could and should have
12	A. I believe so.	12	known about the potential formation of
13	Q. Unless I missed it, I don't	13	NDMA and NDEA in the manufacturing
14	see the deposition -- hang on.	14	processes and that Dr. Xue is incorrect
15	No, I take it back. I see	15	as to what ZHP could and should have
16	on the first page that you saw some	16	known, based on what you read in the
17	deposition transcripts of our -- of the	17	reports and depositions, okay?
18	plaintiffs' experts, Dr. Hecht, Dr. Bain,	18	A. Okay.
19	Dr. Najafi and Dr. Plunkett.	19	Q. If that's the case, then ZHP
20	You read those transcripts?	20	violated cGMP in failing to test for and
21	A. Yes.	21	identify the presence of the NDMA and
22	Q. Did reading those	22	NDEA, correct?
23	transcripts have any impact on your	23	MS. DAVIDSON: I'm going to
24	opinions in this case?	24	object. That's an improper
	Page 271		Page 273
1	A. Did they have any impact?	1	hypothetical. Incomplete and
2	So, obviously, if I read a document, I	2	vague.
3	will have to consider what is being asked	3	THE WITNESS: So I'm looking
4	and what is being said. And if I	4	at the totality of the statements
5	consider that in my deliberations, does	5	by Dr. Hecht and Dr. Najafi. And
6	it have an impact? Yes. Does it have a	6	there are statements that I simply
7	supreme impact, a perfect impact? The	7	cannot subscribe to. And yet you
8	answer is -- is no.	8	ask me to hypothetically accept
9	So, again, I've read them.	9	those as correct.
10	I've read them. I've looked at the	10	If I assume those are
11	questions, and I've looked at the	11	correct, then I don't even know
12	answers.	12	whether that would exclude
13	Q. I'd like you to assume for a	13	Dr. Xue's conclusions.
14	second that the information necessary for	14	However, I cannot -- I
15	ZHP to understand the potential formation	15	struggle to accept statements made
16	of NDMA and NDEA in its valsartan	16	by Dr. Najafi and Dr. Hecht.
17	manufacturing processes was available and	17	That's my struggle.
18	should have been found by the people that	18	BY MR. SLATER:
19	were developing that process and then	19	Q. If ZHP could have and should
20	overseeing that process.	20	have identified the potential formation
21	In other words, I'd like you	21	of NDMA and NDEA in the TEA with sodium
22	to assume that Dr. Hecht and Dr. Najafi	22	nitrite quenching and zinc chloride
23	are correct and that Dr. Xue is incorrect	23	processes and then did absolutely no
24	on that point.	24	testing to try to identify whether there

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<sup>1</sup> was NDMA or NDEA, they would have  
<sup>2</sup> violated cGMPs, correct?  
<sup>3</sup> MS. DAVIDSON: Objection.  
<sup>4</sup> THE WITNESS: If they could  
<sup>5</sup> have and they should have, that  
<sup>6</sup> they -- the struggle that I have  
<sup>7</sup> is, again, as per FDA's statement,  
<sup>8</sup> nobody knew -- or, let's be  
<sup>9</sup> specific, neither industry nor the  
<sup>10</sup> regulators knew, and it's not only  
<sup>11</sup> FDA it's also the European  
<sup>12</sup> regulators, they did not know.  
<sup>13</sup> And, therefore, if you do  
<sup>14</sup> not know, since they didn't know,  
<sup>15</sup> they weren't looking for it.  
<sup>16</sup> So, you know, even based on  
<sup>17</sup> a hypothesis or a hypothetical --  
<sup>18</sup> not hypothesis, a hypothetical  
<sup>19</sup> that a firm knew, what about FDA?  
<sup>20</sup> Was FDA colluding with them? No.  
<sup>21</sup> FDA didn't know either because the  
<sup>22</sup> knowledge of the process was not  
<sup>23</sup> known at that time. And if it was  
<sup>24</sup> not known, then they would not

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THE WITNESS: I'm -- I'm  
stuck at the beginning of your  
question, where you say any set of  
facts as hypotheticals. Facts are  
not hypotheticals. Facts are  
facts.

So the question is, what  
facts are there that you would  
like to present to me and I will  
respond to it?

My struggle is with  
hypotheticals. Yes, hypotheticals  
can go whichever way they are  
presented. But the case here is  
not based on hypotheticals.

If I'm in a deposition, my  
goal, my objective, is for my  
testimony to be accurate.

BY MR. SLATER:

Q. Is it your opinion that even  
if ZHP had known that NDMA and NDEA could  
form in these manufacturing processes,  
knew how the -- let me ask it  
differently.

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<sup>1</sup> have tested for it.  
<sup>2</sup> In fact, again, as stated by  
<sup>3</sup> the FDA, the test methods were not  
<sup>4</sup> there for detecting NDMA because  
<sup>5</sup> nobody expected that NDMA was  
<sup>6</sup> being formed in these processes.  
<sup>7</sup> BY MR. SLATER:  
<sup>8</sup> Q. Is there any state of facts  
<sup>9</sup> that I can tell you as to what ZHP --  
<sup>10</sup> rephrase.  
<sup>11</sup> Is there any set of facts  
<sup>12</sup> that I can present to you as a  
<sup>13</sup> hypothetical as to ZHP's knowledge about  
<sup>14</sup> the manufacturing processes specific to  
<sup>15</sup> the formation of NDMA and NDEA where you  
<sup>16</sup> would say, well, if ZHP had known that,  
<sup>17</sup> then, yes, I agree they violated cGMP in  
<sup>18</sup> connection with those manufacturing  
<sup>19</sup> processes?  
<sup>20</sup> What would I have to show  
<sup>21</sup> you for you to say, yes, I can say they  
<sup>22</sup> violated cGMPs?  
<sup>23</sup> MS. DAVIDSON: Objection.  
<sup>24</sup> Vague.

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<sup>1</sup> If Ethicon -- Ethicon,  
<sup>2</sup> that's funny.  
<sup>3</sup> If ZHP knew that -- let me  
<sup>4</sup> start over.  
<sup>5</sup> If ZHP knew that the  
<sup>6</sup> substances they were using in the sodium  
<sup>7</sup> nitrite with quenching and zinc chloride  
<sup>8</sup> processes could have the reactions that  
<sup>9</sup> they ultimately were proven to have and  
<sup>10</sup> that NDMA and NDEA could potentially  
<sup>11</sup> form, as it ultimately did, if they had  
<sup>12</sup> identified that, if they had identified  
<sup>13</sup> those potential reactions, identified  
<sup>14</sup> that those chemicals and substances would  
<sup>15</sup> be in the process and knew that this  
<sup>16</sup> could happen, if they knew that and then  
<sup>17</sup> did not test to see if there was NDMA and  
<sup>18</sup> NDEA in those -- being produced by those  
<sup>19</sup> processes, under that hypothetical, would  
<sup>20</sup> you say that, well, if they knew those  
<sup>21</sup> things, yes, they violated cGMP by not  
<sup>22</sup> testing for NDMA and NDEA?  
<sup>23</sup> MS. DAVIDSON: Objection.  
<sup>24</sup> THE WITNESS: Again, that's

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1 a hypothetical. So I really need  
 2 to characterize my response  
 3 correctly.

4 If any firm knew of its  
 5 processes resulting in mutagenic  
 6 properties, I believe that firm  
 7 would inform the regulators and  
 8 would not continue production,  
 9 which is what ZHP did.

10 BY MR. SLATER:

11 Q. Taking your response, if ZHP  
 12 knew that the NDMA and NDEA could  
 13 potentially be formed but they weren't  
 14 sure if it was or was not being formed  
 15 and the only way to know would be to  
 16 actually test the valsartan that was  
 17 being produced to see if there was NDMA  
 18 and NDEA but they never did the test,  
 19 under that circumstance, would they  
 20 violate cGMP?

21 MS. DAVIDSON: Objection.

22 THE WITNESS: So if a firm,  
 23 ZHP, knew that NDEA and NDMA were  
 24 being formed in one of the

1 misunderstood.

2 THE WITNESS: So it's  
 3 worthwhile to look at the way the  
 4 pharmaceutical industry operates,  
 5 or is expected to operate.

6 A firm, ZHP included, would  
 7 develop a drug substance process  
 8 away from the manufacturing  
 9 facility, in an R&D setting. They  
 10 would investigate the process.  
 11 They would assess whether the  
 12 process is likely to produce,  
 13 specifically, NDMA and NDEA.

14 And if there is -- their  
 15 assessment is not effectively  
 16 looking -- if their assessment  
 17 says, the potential of forming  
 18 these impurities is not there, as  
 19 per GMP practices, there is no  
 20 obligation to go digging and  
 21 looking for those impurities.

22 All of that is documented in  
 23 ZHP. ZHP documented the process  
 24 of looking at the process, looking

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1 processes, then according to the  
 2 existing quality system  
 3 requirements of any firm, they  
 4 would have to raise a deviation,  
 5 they would have to stop it --  
 6 since it was NDMA and NDEA, they  
 7 would then effectively stop  
 8 manufacture and stop shipping.

9 This happened in June 2018  
 10 when they became aware. Prior to  
 11 that, they didn't know.

12 BY MR. SLATER:

13 Q. If they understood that it  
 14 was possible for the NDMA and NDEA to  
 15 form, if they understood that and  
 16 understood the potential mechanism of  
 17 formation that ultimately was proven to  
 18 have occurred, would cGMPs, at that time,  
 19 have required ZHP to then do tests then  
 20 to see if there was NDMA and NDEA being  
 21 created?

22 MS. DAVIDSON: Objection. I  
 23 think this was asked and answered.  
 24 If it's different, I

1 at potential impurities and  
 2 actually testing for what they  
 3 knew and coming up with a list of  
 4 them which was compliant to FDA  
 5 requirements.

6 They submitted that change  
 7 as a change to the DMF to FDA.  
 8 That was reviewed by FDA. FDA  
 9 accepted the change.

10 That process, then, got --  
 11 effectively, in 2018, the client,  
 12 a potential client -- not a  
 13 client, a potential client,  
 14 Novartis, told them that, hey,  
 15 what is this peak? Let's look at  
 16 it. They looked at it, they said  
 17 it's NDMA.

18 Immediately, they took  
 19 action of reporting to FDA,  
 20 stopping the process, stop  
 21 selling, did the recall, changed  
 22 the process, submitted the process  
 23 to the FDA.

24 That's why the DMF is still

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1 active. The DMF is active with a  
 2 change to the process.

3 BY MR. SLATER:

4 Q. Can you answer my question,  
 5 please?

6 Doctor, can you please  
 7 answer my question? I would really  
 8 appreciate it.

9 A. So that I'm clear, can you  
 10 please repeat your question? Because I  
 11 believe I've answered it.

12 Q. If ZHP -- actually, you know  
 13 what, I'll ask the court reporter to read  
 14 it back to you so we'll get it exact.

15 And I really ask you, can  
 16 you just answer the question I actually  
 17 asked you?

18 COURT REPORTER: I think  
 19 Jessica was kicked off.

20 THE WITNESS: I would like  
 21 to wait until she's back, please.

22 MR. SLATER: Go off the  
 23 record.

24 VIDEO TECHNICIAN: We're off

1 developing the process happens  
 2 away from the manufacturing  
 3 facility.

4 When ZHP was developing the  
 5 process away from the  
 6 manufacturing facility, they did  
 7 consider the formation of  
 8 impurities. And at that time, as  
 9 per FDA's statement that neither  
 10 FDA nor industry understood the  
 11 pathway for formation of NDMA,  
 12 these were not considered nor  
 13 detected.

14 So -- and, again, continuing  
 15 with what I said before,  
 16 development of a process is not a  
 17 GMP process, it's a non-GMP. It's  
 18 not regulated.

19 Once it is approved by the  
 20 regulator and it's a process which  
 21 is validated, then it becomes a  
 22 GMP process and it's then in the  
 23 manufacturing markets -- markets  
 24 process.

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1 the record at 3:56 p.m.  
 2 - - -

3 (Whereupon, a brief recess  
 4 was taken.)  
 5 - - -

6 VIDEO TECHNICIAN: We're  
 7 back on the record at 4:04 p.m.

8 BY MR. SLATER:

9 Q. If ZHP understood the  
 10 possible formation of NDMA and NDEA with  
 11 its valsartan processes -- let me start  
 12 over.

13 If ZHP had understood that  
 14 the substances it was introducing into  
 15 the valsartan manufacturing processes,  
 16 specifically TEA with sodium nitrite  
 17 quenching and zinc chloride, could  
 18 potentially cause the formation of NDMA  
 19 and NDEA, were they required by cGMP to  
 20 test to see if NDMA and NDEA was formed?

21 MS. DAVIDSON: Objection.

22 THE WITNESS: So I did  
 23 respond to that question.

24 The response was that

1 So your question asks --  
 2 your question has hypotheticals  
 3 that, you know, I would have to  
 4 conclude to do away with all facts  
 5 and work in the ether of  
 6 hypotheticals.

7 BY MR. SLATER:

8 Q. When the process changes  
 9 took place, that's governed by GMP, it's  
 10 called change control, right?

11 A. Yes.

12 Q. If, as part of the process  
 13 changes, ZHP had realized that the  
 14 chemicals they were using and the  
 15 substances they were using could form  
 16 NDMA and NDEA under the conditions of  
 17 those processes, if they had realized  
 18 that, were they required, by cGMPs, to  
 19 test to see if there was NDMA or NDEA in  
 20 the valsartan?

21 A. So giving you, again, almost  
 22 a repeat answer.

23 For ZHP to actually change  
 24 their process using a change control

<p>1 procedure, they cannot do it in the 2 manufacturing facility.</p> <p>3 What they have to do is 4 develop the process away from the 5 manufacturing facility, then validate the 6 process at scale in the manufacturing 7 facility and discard that batch.</p> <p>8 Then submit that to the 9 agency, get approval from the agency and 10 EDQM, because that was also the customer, 11 and then proceed to manufacture for the 12 market.</p> <p>13 So it's not a case of 14 suddenly one day they decide to implement 15 a change based on a change control. 16 There were two years of investigations and 17 studies carried out before that change 18 control was actually implemented, which 19 was after approval by the FDA.</p> <p>20 Q. I'll ask the question 21 differently.</p> <p>22 If ZHP had realized, at any 23 point between 2011 and 2018, that their 24 manufacturing processes for the</p>	<p>Page 286</p> <p>1 you when they figured out that it was 2 there.</p> <p>3 I said if they figured out 4 that it was possibly forming, did they 5 need to do the tests, at that point in 6 time when they first realized it could 7 possibly be forming, to see if there was 8 NDMA or NDEA in the drug substance; yes 9 or no?</p> <p>10 MS. DAVIDSON: I'm going to 11 object, because you interrupted 12 the witness and are asking the 13 same question again. So it's 14 asked and answered.</p> <p>15 But please don't interrupt 16 Dr. Afnan.</p> <p>17 THE WITNESS: You know, so 18 if I'd like to go to my report. I 19 would like -- because I address 20 this in my report, and I think 21 that is probably -- if you go to 22 Number 80 in my report.</p> <p>23 It says, ZHP performed 24 extensive research and testing for</p>
<p>1 manufacture of valsartan, the TEA with 2 sodium nitrite quenching and the zinc 3 chloride process, could potentially be 4 creating NDMA and NDEA, as soon as they 5 made that -- had that revelation that the 6 process could create those genotoxic 7 impurities, would they have been required 8 to test to see if there was NDMA and 9 NDEA?</p> <p>10 MS. DAVIDSON: Objection. 11 Same objections.</p> <p>12 THE WITNESS: So when 13 they -- when ZHP identified 14 presence of NDMA in its valsartan, 15 it actually stopped manufacture. 16 It informed the FDA. It put a 17 stop at the process on hold. It 18 put the stock on hold. It 19 requested FDA for a recall 20 classification. So they did all 21 of that.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. That's great. That's not 24 what I asked you, though. I didn't ask</p>	<p>Page 287</p> <p>1 more than two years before 2 submitting the drug master file 3 amendment containing zinc chloride 4 process. On June 16th, 2011, ZHP 5 issued a summary of its test 6 production using the zinc chloride 7 process that noted overall the 8 crude isomer of the tri production 9 batches were maintained at 1 to 2 10 percent and there were no 11 individual impurities that were 12 difficult to remove by 13 crystallization and purification. 14 Therefore, the product quality 15 also met the expected 16 requirements.</p> <p>17 Likewise, an internal change 18 request form, dated November 27, 19 2011, stated that the new process 20 solves the problem of production 21 stability and Valine methyl ester 22 condensation and pentanoyl reaction 23 and the new reaction system of 24 zinc chloride and DMF for</p>

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1 tetrazole reaction is developed,  
2 which greatly improves the  
3 conversion rate of raw materials,  
4 improves the yields, reduces --  
5 reduces -- improves and -- it says  
6 reduces the heat and reduces the  
7 free waste. In addition, by  
8 optimizing the saponification  
9 condition, the assay of isomer in  
10 valsartan crude is reduced and the  
11 quality of valsartan is improved.  
12 Through a large number of  
13 experimental results about  
14 optimizing process and combined  
15 with theoretical analysis, the  
16 synthesis route of new process and  
17 critical process parameters are  
18 initially -- initially determined  
19 by Huahai and the preliminary  
20 analysis and evaluation of  
21 impurities in the new process is  
22 completed, confirming that the  
23 quality product risk is  
24 controlled.

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1 Your counsel is making crazy faces. I  
2 don't know why.  
3 I asked you a very  
4 straightforward question and you went and  
5 read me this whole section of your report  
6 for five minutes. I'm not really sure  
7 why you think that's beneficial to your  
8 position here.  
9 So can you now answer my  
10 question? Which what you just read has  
11 nothing to do with.  
12 Can you please answer my  
13 question?  
14 A. What was your question?  
15 Q. It's literally a yes-or-no  
16 question, a very straightforward  
17 hypothetical.  
18 Can you just answer it,  
19 please?  
20 MS. DAVIDSON: There's no  
21 question pending. He answered the  
22 question you asked.  
23 If you want to ask another  
24 question, please go ahead.

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1 At the same time, the safety  
2 risk brought by process changes  
3 are also evaluated by Huahai  
4 confirming that the new process is  
5 safe and reliable, essentially.  
6 According to the above  
7 analysis, the zinc chloride  
8 process is stable and reliable and  
9 has the conditions for further  
10 validation of production. The  
11 changes of original process are  
12 applied and a new process  
13 validation is organized.  
14 And all of this was  
15 submitted to FDA.  
16 BY MR. SLATER:  
17 Q. Answer my question, please.  
18 I'm going to ask you now --  
19 I know your counsel is not going to tell  
20 you that what you just did is completely  
21 obstructive and not responsive. I  
22 realize that. I'm just -- I'm just  
23 telling you that this is not appropriate.  
24 I asked you a question.

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1 BY MR. SLATER:  
2 Q. I asked the question.  
3 Doctor, please just answer  
4 it. Come on.  
5 MS. DAVIDSON: Objection.  
6 If you want him to answer a  
7 question --  
8 MR. SLATER: Don't tell me  
9 to ask a question, please. Don't  
10 give me instructions. I don't  
11 need to be told what to do.  
12 MS. DAVIDSON: There's no  
13 question pending. You asked a  
14 question. He answered it.  
15 MR. SLATER: I don't want to  
16 talk to you. I don't want to  
17 speak to you. It's not helpful.  
18 It's wasting more time.  
19 BY MR. SLATER:  
20 Q. So, Doctor, answer my  
21 question, please.  
22 MS. DAVIDSON:  
23 Unfortunately, I'm the person  
24 defending this deposition. You're

<p>1 interrupting me. You're being 2 rude.</p> <p>3 Dr. Afnan answered your 4 question.</p> <p>5 If you have another 6 question, ask another question. 7 But you can't just say, I don't 8 like your answer, give me another 9 one.</p> <p>10 MR. SLATER: All right, 11 counsel. You stand behind that 12 being responsive. That's fine.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. Now, Doctor, answer my 15 question.</p> <p>16 If ZHP, at any point between 17 2011 and 2018, realized that their 18 manufacturing processes for valsartan 19 could potentially be creating NDMA and 20 NDEA and they realized what the potential 21 mechanism of formation was, at that 22 point, were they required to test to see 23 if there was NDMA or NDEA in the 24 valsartan; yes or no?</p>	<p>Page 294</p> <p>1 be NDMA in ZHP's valsartan, correct? 2 A. Novartis informed ZHP 3 that -- on 6th of June, informed ZHP that 4 they had asked -- to investigate an 5 unknown impurity. ZHP also, in parallel, 6 started an investigation of that same 7 issue.</p> <p>8 So it was actually then that 9 they both came to the same conclusion. 10 And Novartis actually doesn't say here 11 NDMA, Novartis says this is potentially 12 NDMA.</p> <p>13 Q. Could ZHP have figured out 14 that there was NDMA in its valsartan 15 without Novartis's involvement? Would 16 that have been possible for ZHP to do 17 that all by itself?</p> <p>18 MS. DAVIDSON: Objection.</p> <p>19 THE WITNESS: This was a 20 manufacturing process which had 21 been approved by the Europeans and 22 FDA. The analytical method was 23 effectively GC FID that was not 24 detecting NDMA.</p>
<p>1 MS. DAVIDSON: Objection.</p> <p>2 THE WITNESS: I'm afraid I 3 can't give you a yes-or-no answer. 4 So I'll give you an answer.</p> <p>5 The answer is, based on the 6 hypotheticals that you have posed 7 and the assumptions that you have 8 made, the answer would be yes.</p> <p>9 But this is not the case 10 here. I do not subscribe to the 11 hypotheticals. And I do not 12 subscribe to the assumptions.</p> <p>13 And, again, this was not the 14 case here with ZHP prior to June 15 2018.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. There came a date when 18 Novartis advised ZHP that Novartis 19 thought there might be NDMA in the 20 valsartan, correct?</p> <p>21 A. Sorry. Can you ask the 22 first part? It just got cut out.</p> <p>23 Q. Novartis notified ZHP, in 24 2018, that it believed that there might</p>	<p>Page 295</p> <p>1 FDA says that. The methods 2 were not there. And nobody knew 3 about the formation of NDMA in 4 valsartan, so.</p> <p>5 BY MR. SLATER:</p> <p>6 Q. Is an important part of the 7 basis for your opinion what the FDA said 8 in the statements that it issued about 9 this situation, about what people knew 10 and what people didn't know, and 11 different methods and all the things that 12 the FDA has said? Is that an important 13 part of your opinion?</p> <p>14 A. Yes.</p> <p>15 Q. Could ZHP have figured out 16 that there was NDMA in the valsartan 17 without Novartis's assistance? Was that 18 possible, that they could have done it on 19 their own?</p> <p>20 MS. DAVIDSON: Objection.</p> <p>21 THE WITNESS: The question 22 is whether ZHP could have 23 identified it? And the answer is, 24 what was the justification to go</p>

<p>1 and look for it?</p> <p>2 Novartis had a reason to 3 look for it, based on what has 4 been shared, which is, here is a 5 little peak which is coming up, 6 and unknown impurity after 7 targeting, and it was below the .1 8 percent and Novartis said, can we 9 look at that one?</p> <p>10 Now, there were other 11 unknown peaks as well, which 12 Novartis did not look at. But 13 Novartis decided to look at that.</p> <p>14 BY MR. SLATER:</p> <p>15 Q. ZHP could have noticed that 16 peak and investigated that peak without 17 being told anything by Novartis; that was 18 possible, right?</p> <p>19 A. ZHP was operating according 20 to Q3A, which said you can have unknown 21 impurities below .1 percent.</p> <p>22 So the answer is, they could 23 have. But they had no reason, no 24 justification, no cause to look for that</p>	<p>Page 298</p> <p>1 just a lot smarter than the people at 2 ZHP?</p> <p>3 MS. DAVIDSON: Objection.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. Is that why they figured it 6 out and ZHP didn't?</p> <p>7 MS. DAVIDSON: I'm sorry. I 8 objected after the first question 9 because I thought there was just 10 one question. And then there was 11 a second question.</p> <p>12 I object to both.</p> <p>13 THE WITNESS: I cannot 14 comment whatsoever on that. 15 That's beyond the scope of my 16 work, to guess who is smarter.</p> <p>17 BY MR. SLATER:</p> <p>18 Q. ZHP could have looked at the 19 unknown peaks and could have investigated 20 them and could have figured out that one 21 of those peaks represented NDMA if it had 22 chosen to do a thorough investigation 23 like Novartis did, correct?</p> <p>24 MS. DAVIDSON: Objection.</p>
<p>1 impurity and that peak.</p> <p>2 Q. If ZHP had been more careful 3 than it actually was and had decided to 4 investigate that NDMA peak, which it had 5 not identified yet, ZHP could have 6 figured out that it was NDMA, right?</p> <p>7 That was something that was technically 8 feasible for it to do, correct?</p> <p>9 MS. DAVIDSON: Objection.</p> <p>10 THE WITNESS: So if you know 11 what you're looking for, it is 12 feasible to do it. ZHP looked 13 with GCMS and actually -- so 14 that's how the conversation with 15 Novartis started.</p> <p>16 Novartis asked for, can you 17 send the data, the spectra for 18 that peak? Which they did and 19 they sent in. And that 20 effectively was not NDMA; that was 21 the conclusion that they both came 22 to.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. Were the people at Novartis</p>	<p>Page 299</p> <p>1 BY MR. SLATER:</p> <p>2 Q. ZHP had the ability to do 3 that if it chose to go through that 4 process, correct?</p> <p>5 MS. DAVIDSON: Again, I keep 6 objecting after one question and 7 then a second question gets asked. 8 I'm objecting to both.</p> <p>9 THE WITNESS: ZHP had no 10 reason to investigate, because 11 they were adhering to the GMPs and 12 the requirements of FDA and EDQM. 13 They were following the GMPs.</p> <p>14 And, therefore, what was 15 going on was that you were 16 allowed -- or ZHP was allowed to 17 have unknown impurities below .1 18 percent. This is common practice 19 in industry.</p> <p>20 BY MR. SLATER:</p> <p>21 Q. You keep explaining this to 22 me. It's a very simple question. 23 Could ZHP have identified 24 the NDMA peak without Novartis's help if</p>

<p style="text-align: right;">Page 302</p> <p><sup>1</sup> ZHP had actually gone through the thought <sup>2</sup> process that Novartis did? Was that <sup>3</sup> possible?</p> <p><sup>4</sup> MS. DAVIDSON: Objection. <sup>5</sup> Asked and answered.</p> <p><sup>6</sup> THE WITNESS: It's a simple <sup>7</sup> question, and you don't like my <sup>8</sup> answer.</p> <p><sup>9</sup> Because my answer is, there <sup>10</sup> was no cause for ZHP to <sup>11</sup> investigate the unknown peaks. <sup>12</sup> There had been no cause from the <sup>13</sup> regulators to investigate those <sup>14</sup> unknown peaks, not -- two <sup>15</sup> regulators.</p> <p><sup>16</sup> BY MR. SLATER:</p> <p><sup>17</sup> Q. Then why did Novartis <sup>18</sup> investigate the unknown peaks?</p> <p><sup>19</sup> A. Novartis was -- sorry.</p> <p><sup>20</sup> THE WITNESS: Jessica?</p> <p><sup>21</sup> MR. SLATER: Are you asking <sup>22</sup> for an objection, Doctor? I <sup>23</sup> mean --</p> <p><sup>24</sup> THE WITNESS: If she wants</p>	<p style="text-align: right;">Page 304</p> <p><sup>1</sup> A. I can't answer whether <sup>2</sup> Novartis was super human or not. <sup>3</sup> Q. Okay. Then you can't answer <sup>4</sup> the question. That's fine.</p> <p><sup>5</sup> Doctor, one of the very <sup>6</sup> important foundational assumptions in <sup>7</sup> your opinion is that Q3A allowed the NDMA <sup>8</sup> peak to go uninvestigated because it was <sup>9</sup> below .1 percent.</p> <p><sup>10</sup> Do I understand that opinion <sup>11</sup> correctly?</p> <p><sup>12</sup> A. No, you do not understand <sup>13</sup> that correctly. I have never said that <sup>14</sup> Q3A allows NDMA to be ignored.</p> <p><sup>15</sup> If you see it in Q3A, I <sup>16</sup> would appreciate you showing it to me.</p> <p><sup>17</sup> Q. You've told -- you've told <sup>18</sup> me that the NDMA peak was so small and it <sup>19</sup> was below .1 percent, so ZHP was not <sup>20</sup> required to investigate what the cause of <sup>21</sup> that peak was; that's your opinion, <sup>22</sup> right?</p> <p><sup>23</sup> MS. DAVIDSON: Objection. <sup>24</sup> That completely mischaracterizes</p>
<p style="text-align: right;">Page 303</p> <p><sup>1</sup> to.</p> <p><sup>2</sup> MS. DAVIDSON: He was <sup>3</sup> apologizing for the fact that I <sup>4</sup> had asked earlier to wait before <sup>5</sup> he answered questions.</p> <p><sup>6</sup> I would have objected to the <sup>7</sup> question. But go ahead.</p> <p><sup>8</sup> MR. SLATER: I have another <sup>9</sup> question. I'm sure you would <sup>10</sup> have.</p> <p><sup>11</sup> BY MR. SLATER:</p> <p><sup>12</sup> Q. Did Novartis do something <sup>13</sup> that was super human in the <sup>14</sup> pharmaceutical field --</p> <p><sup>15</sup> MS. DAVIDSON: Objection.</p> <p><sup>16</sup> BY MR. SLATER:</p> <p><sup>17</sup> Q. -- that no other company <sup>18</sup> would have ever done, but we just -- <sup>19</sup> everybody just lucked out that Novartis <sup>20</sup> happened to get involved?</p> <p><sup>21</sup> MS. DAVIDSON: Objection.</p> <p><sup>22</sup> BY MR. SLATER:</p> <p><sup>23</sup> Q. Answer the question, please; <sup>24</sup> yes or no.</p>	<p style="text-align: right;">Page 305</p> <p><sup>1</sup> his testimony.</p> <p><sup>2</sup> THE WITNESS: It does. No, <sup>3</sup> that's not what I said.</p> <p><sup>4</sup> BY MR. SLATER:</p> <p><sup>5</sup> Q. Okay. So was ZHP required <sup>6</sup> to investigate what was behind that peak <sup>7</sup> that ultimately turned out to be NDMA <sup>8</sup> under cGMP; yes or no?</p> <p><sup>9</sup> A. I have responded to that <sup>10</sup> question.</p> <p><sup>11</sup> Q. Yes or no?</p> <p><sup>12</sup> MS. DAVIDSON: Objection. <sup>13</sup> Yes or no is not a question.</p> <p><sup>14</sup> THE WITNESS: Yeah, I cannot <sup>15</sup> give you a yes-or-no answer. And <sup>16</sup> the response I've given you, you <sup>17</sup> don't like.</p> <p><sup>18</sup> BY MR. SLATER:</p> <p><sup>19</sup> Q. That's fine.</p> <p><sup>20</sup> MR. SLATER: This is <sup>21</sup> Exhibit-12, right? Just let me <sup>22</sup> know when you know.</p> <p><sup>23</sup> MS. DAVIDSON: Are you <sup>24</sup> talking to us?</p>

<p>1           MR. SLATER: No, I'm not      2 talking to you.      3           MS. DAVIDSON: Okay.      4           - - -      5           (Whereupon, Exhibit      6 Afnan-12, No Bates, 10/25/06      7 Impurities in New Drug Substances      8 Q3A(R2), was marked for      9 identification.)      10          - - -      11 BY MR. SLATER:      12 Q. This is Exhibit-12.      13 A. Yes.      14 Q. We've put on the screen the      15 ICH Q3A.      16 Do you see that?      17 A. Yes.      18 Q. That's the Q3A that you've      19 been -- or the Q3 that you've been      20 referring to the whole deposition, right?      21 A. Yes.      22 MS. DAVIDSON: Objection.      23 Please, Dr. Afnan --      24 THE WITNESS: Yes.</p>	<p>Page 306</p> <p>1           3.1.      2           Under Section 3, which is      3 titled, Rationale for the Reporting and      4 Control of Impurities, there's 3.1,      5 Organic Impurities.      6           Do you see that?      7           A. Yes.      8           Q. This says, The      9 application -- The applicant should --      10 rephrase.      11           3.1 says, The applicant      12 should summarize the actual and potential      13 impurities most likely to arise during      14 the synthesis, purification and storage      15 of the new drug substance. This summary      16 should be based on sound scientific      17 appraisal of the chemical reactions      18 involved in the synthesis, impurities      19 associated with raw materials that could      20 contribute to the impurity profile of the      21 new drug substance, and possible      22 degradation products.      23           Do you see that?      24           A. Yes.</p>
<p>Page 307</p> <p>1           MS. DAVIDSON: -- give me      2 time to object.      3 BY MR. SLATER:      4           Q. Even though this says that      5 it's impurities in new drug substances,      6 you're aware that there's a guidance for      7 industry, from June 2009, that indicates      8 that this is also applicable to ANDAs,      9 right?      10          A. Please tell me which      11 guidance.      12          Q. Let me just ask you this      13 way: You, as the expert on GMP, do you      14 know whether or not this guidance is also      15 applicable not only to new drug      16 substances but also to ANDAs?      17          A. Q3A, right?      18          Q. Yep.      19          A. Yes, it is.      20          Q. Okay. This is an important      21 document that you're relying on in      22 forming your opinions, right?      23          A. Yes.      24          Q. Let's go to Page 2, Section</p>	<p>Page 309</p> <p>1           Q. So according to this      2 standard, among other things, ZHP was      3 required to make a sound scientific      4 appraisal of impurities associated with      5 the raw materials, correct?      6           A. Yes.      7           Q. And, for example, with DMF      8 that would include dimethylamine; that      9 would be an impurity associated with a      10 raw material, right?      11          MS. DAVIDSON: Objection.      12 BY MR. SLATER:      13          Q. Right, Doctor?      14          A. Okay. Yes.      15          Q. Possible degradation      16 products, that's another thing that this      17 required ZHP to make a sound scientific      18 appraisal of, right?      19          MS. DAVIDSON: Objection.      20          THE WITNESS: They did.      21 BY MR. SLATER:      22          Q. That's what this document      23 says they were required to do.      24          I didn't ask what they did,</p>

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1 Doctor. So let's now start answering my  
 2 questions, when I'm down to a few hours.  
 3 A. Okay.  
 4 MS. DAVIDSON: Objection.  
 5 If that's a question.  
 6 BY MR. SLATER:  
 7 Q. It says, They were also  
 8 required to make a sound scientific  
 9 appraisal of possible degradation  
 10 products, correct?  
 11 MS. DAVIDSON: Objection.  
 12 Misstates the document.  
 13 BY MR. SLATER:  
 14 Q. That's what it says, right?  
 15 MS. DAVIDSON: Objection.  
 16 THE WITNESS: It says, The  
 17 summary should be based on sound  
 18 scientific appraisal of the  
 19 chemical reactions involved in the  
 20 synthesis, impurities associated  
 21 with the raw materials that could  
 22 contribute to the impurity profile  
 23 of the new drug substance, and  
 24 possible degradation products.

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1 That misstates his testimony  
 2 again.  
 3 BY MR. SLATER:  
 4 Q. Correct?  
 5 A. I do not rely only and  
 6 solely on this statement which you have  
 7 here.  
 8 I believe ZHP did do a  
 9 thorough job of looking at its processes.  
 10 Q. Did ZHP ever, to your  
 11 knowledge, try to figure out what the  
 12 peak was, the one that was NDMA, that we  
 13 later learned was NDMA, did they ever try  
 14 to identify what that peak was before  
 15 Novartis got in touch with them; yes or  
 16 no?  
 17 It's a factual question, did  
 18 they or didn't they?  
 19 MS. DAVIDSON: Objection.  
 20 THE WITNESS: The answer is  
 21 right at the top of the page. If  
 22 you scroll to just below 3.1,  
 23 please.  
 24 BY MR. SLATER:

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1 BY MR. SLATER:  
 2 Q. Look down now two more  
 3 paragraphs.  
 4 There's a paragraph at the  
 5 bottom of this section that starts --  
 6 MR. SLATER: You've got to  
 7 scroll down a little bit, Chris.  
 8 BY MR. SLATER:  
 9 Q. Looking now at the last  
 10 paragraph in Section 3.1, it says,  
 11 Identification of impurities present at  
 12 an apparent level of not more than, less  
 13 than or equal to, the identification  
 14 threshold is generally not considered  
 15 necessary.  
 16 Do you see that?  
 17 A. Yes.  
 18 Q. And that's one of the  
 19 important things that you've been relying  
 20 on throughout your testimony today as to  
 21 why you believe ZHP did not have to do  
 22 any tests to identify the peak that  
 23 turned out to be NDMA, correct?  
 24 MS. DAVIDSON: Objection.

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1 Q. Doctor, I asked if they  
 2 tried to identify what that peak was.  
 3 This document doesn't talk about ZHP.  
 4 Did they try to identify  
 5 what that peak was or not; yes or no?  
 6 MS. DAVIDSON: You  
 7 interrupted the witness. And I'm  
 8 objecting.  
 9 MR. SLATER: How about you  
 10 ask your witness, please, to  
 11 answer the question directly, as  
 12 opposed to asking to talk about  
 13 this document where the answer is  
 14 not found.  
 15 THE WITNESS: You point me  
 16 to this document and you said,  
 17 based on this, they should have.  
 18 And I'm pointing --  
 19 BY MR. SLATER:  
 20 Q. That's not what I asked you.  
 21 My question was very direct, Doctor.  
 22 I asked you is --  
 23 A. You --  
 24 Q. -- there anything that

<p>Page 314</p> <p><sup>1</sup> you've seen indicating that ZHP ever  <sup>2</sup> tried to identify what that NDMA peak was  <sup>3</sup> before June of 2018?</p> <p><sup>4</sup> A. The applicant should  <sup>5</sup> summarize the actual and potential  <sup>6</sup> impurities most likely to arise during  <sup>7</sup> the synthesis, purification and storage  <sup>8</sup> of the new product. This summary should  <sup>9</sup> be based on sound scientific appraisal.</p> <p><sup>10</sup> They did do that.</p> <p><sup>11</sup> Based on that -- based on  <sup>12</sup> that scientific appraisal by ZHP over two  <sup>13</sup> years, as I have read to you a few  <sup>14</sup> minutes ago, maybe ten minutes ago, as I  <sup>15</sup> read that, this was done.</p> <p><sup>16</sup> Q. So you're saying that ZHP  <sup>17</sup> actually evaluated the unknown peak that  <sup>18</sup> later turned out to be NDMA --</p> <p><sup>19</sup> MS. DAVIDSON: Objection.</p> <p><sup>20</sup> BY MR. SLATER:</p> <p><sup>21</sup> Q. -- to try to figure out what  <sup>22</sup> it was before June of 2018?</p> <p><sup>23</sup> MS. DAVIDSON: Objection.</p> <p><sup>24</sup> THE WITNESS: That's not</p>	<p>Page 316</p> <p><sup>1</sup> was that turned out to be NDMA before  <sup>2</sup> Novartis got in touch with it?</p> <p><sup>3</sup> As a matter of fact, yes or  <sup>4</sup> no, did they actually focus on that peak  <sup>5</sup> and try to identify what it was at any  <sup>6</sup> point before Novartis raised an issue  <sup>7</sup> about it; yes or no?</p> <p><sup>8</sup> MS. DAVIDSON: Objection.</p> <p><sup>9</sup> THE WITNESS: There were  <sup>10</sup> customer requests about peaks --  <sup>11</sup> unknown peaks which was -- this  <sup>12</sup> was one of them that ZHP had  <sup>13</sup> shared information with.</p> <p><sup>14</sup> Even with this peak, which  <sup>15</sup> is effectively a peak on top of  <sup>16</sup> another one, was requested by  <sup>17</sup> Novartis, and ZHP provided the  <sup>18</sup> information to Novartis.</p> <p><sup>19</sup> So did they try? Yes.</p> <p><sup>20</sup> BY MR. SLATER:</p> <p><sup>21</sup> Q. Did other customers identify  <sup>22</sup> that peak and ask what it was, the NDMA  <sup>23</sup> peak, at any point before Novartis did in  <sup>24</sup> 2018; yes or no?</p>
<p>Page 315</p> <p><sup>1</sup> what I said.</p> <p><sup>2</sup> BY MR. SLATER:</p> <p><sup>3</sup> Q. Well, how about you just  <sup>4</sup> give me a straight answer to the  <sup>5</sup> question. I don't understand why you  <sup>6</sup> can't just say yes or no.</p> <p><sup>7</sup> Did they or didn't they try  <sup>8</sup> to identify that peak?</p> <p><sup>9</sup> MS. DAVIDSON: Objection.</p> <p><sup>10</sup> THE WITNESS: There was no  <sup>11</sup> regulatory requirement, there was  <sup>12</sup> no scientific obligation to  <sup>13</sup> identify the peak.</p> <p><sup>14</sup> The reason was because they  <sup>15</sup> looked at the process, and based  <sup>16</sup> on the process, which they looked  <sup>17</sup> at, the prediction was that there  <sup>18</sup> is no undesirable impurity present  <sup>19</sup> in this process. Therefore, the  <sup>20</sup> unknowns would not be required to  <sup>21</sup> be investigated.</p> <p><sup>22</sup> BY MR. SLATER:</p> <p><sup>23</sup> Q. Did ZHP ever, to your  <sup>24</sup> knowledge, try to identify what that peak</p>	<p>Page 317</p> <p><sup>1</sup> MS. DAVIDSON: Objection.</p> <p><sup>2</sup> THE WITNESS: If you had  <sup>3</sup> allowed me to complete my  <sup>4</sup> response, I would have told you  <sup>5</sup> that this was not a question about  <sup>6</sup> is it an NDMA or not.</p> <p><sup>7</sup> The question was, can you  <sup>8</sup> provide us with the data as to  <sup>9</sup> what this peak is? And ZHP  <sup>10</sup> investigated, reported it to them,  <sup>11</sup> and they accepted it.</p> <p><sup>12</sup> BY MR. SLATER:</p> <p><sup>13</sup> Q. Who?</p> <p><sup>14</sup> A. The clients.</p> <p><sup>15</sup> Q. Which one?</p> <p><sup>16</sup> A. There were multiple  <sup>17</sup> questions that came from different  <sup>18</sup> clients, and that's what they did.</p> <p><sup>19</sup> Q. Multiple clients asked  <sup>20</sup> questions about unknown peaks, including  <sup>21</sup> that peak that turned out to be NDMA?</p> <p><sup>22</sup> MS. DAVIDSON: Objection.</p> <p><sup>23</sup> Misstates his testimony.</p> <p><sup>24</sup> Dr. Afnan, give me a minute.</p>

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1 MR. SLATER: I'll withdraw  
 2 that question, actually.

3 MS. DAVIDSON: Okay.

4 MR. SLATER: We'll live with  
 5 the testimony.

6 BY MR. SLATER:

7 Q. All right. Let's go back to  
 8 the document.

9 Looking at the paragraph at  
 10 the end of 3.1, it says, Identification  
 11 of impurities present at an apparent  
 12 level of not more than, less than or  
 13 equal to the identification threshold is  
 14 generally not considered necessary.  
 15 However, analytical procedures should be  
 16 developed for those potential impurities  
 17 that are expected to be unusually potent,  
 18 producing toxic or pharmacological  
 19 effects at a level not more than, less  
 20 than or equal to the identification  
 21 threshold. All impurities should be  
 22 qualified as described later in this  
 23 guideline.

24 Do you see what I just read?

1 used and assumptions made in establishing  
 2 the level of the impurity should be  
 3 clearly stated.

4 Do you see that?

5 A. Can you point me to where it  
 6 is in the second paragraph which begins  
 7 with, A rational?

8 Q. Correct. Seven lines down.  
 9 A. For impurities known to  
 10 be -- okay.

11 Q. That's what the document  
 12 says, correct?

13 A. For impurities known to be  
 14 unusually potent or to produce toxic or  
 15 unexpected pharmacological effects, the  
 16 quantitation/detection limit of the  
 17 analytical procedure should be  
 18 commensurate with the level at which the  
 19 impurities should be controlled.

20 Yes, that's what it says.

21 Q. Now, let's go to Page 10,  
 22 which is Attachment 3, the decision tree  
 23 for identification and qualification.

24 You cited this in your

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1 A. Yes.

2 Q. The potential impurities  
 3 that are expected to be unusually potent  
 4 would include N-nitroso compounds,  
 5 correct?

6 MS. DAVIDSON: Objection.

7 THE WITNESS: N-nitroso  
 8 compounds are compounds of cohorts  
 9 of interest.

10 BY MR. SLATER:

11 Q. Let's go to Page 4, Section  
 12 6.

13 Looking at Section 6,  
 14 Listing of Impurities and Specifications.  
 15 I want to go now to the second paragraph.

16 About halfway down that  
 17 paragraph, it says, For impurities known  
 18 to be unusually potent or to produce  
 19 toxic or unexpected pharmacological  
 20 effects, the quantitation/detection limit  
 21 of the analytical procedures should be  
 22 commensurate with the level at which the  
 23 impurities should be controlled. For  
 24 unidentified impurities, the procedure

1 report, right?

2 A. Yes.

3 Q. I'm just trying to find  
 4 where you cited this.

5 Do you know where this is in  
 6 your report?

7 A. No.

8 Q. All right. Well, that's  
 9 fine. I don't need to find it in your  
 10 report.

11 Do you see at the top --  
 12 rephrase.

13 Do you see at the top of the  
 14 decision tree, the first input says, Is  
 15 impurity greater than identification  
 16 threshold?

17 A. Yes.

18 Q. And it says, No. And if you  
 19 go to no, No action.

20 And if, Yes, then you go  
 21 down to the next question of structure  
 22 identified.

23 Do you see that?

24 A. Yes.

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1 Q. Do you see the little C next  
 2 to the word "threshold" up at the top?  
 3 A. Yes.

4 Q. Yep. And then on the next  
 5 page, let's go to the next page, Footnote  
 6 C says, Lower thresholds can be  
 7 appropriate if the impurity is unusually  
 8 toxic, correct?

9 A. Correct.

10 Q. So ZHP was required to know  
 11 that if it turned out that those peaks  
 12 that were below .1 percent represented  
 13 unusually toxic substances, like  
 14 N-nitroso compounds, that they couldn't  
 15 rely on the threshold of .1 percent; they  
 16 were required by cGMP to know that,  
 17 because that's what it said in the Q3A,  
 18 correct?

19 MS. DAVIDSON: Objection.  
 20 Mischaracterizes the document.

21 THE WITNESS: So if I go  
 22 back to the very first item that  
 23 you showed me in this set, in this  
 24 line of questioning, it says, For

1 issue, they're held to a higher standard  
 2 than an unusually less knowledgeable  
 3 manufacturer that doesn't figure it out  
 4 and doesn't realize, oh, there is this  
 5 potential impurity, they're held to a  
 6 lower standard?

7 Is that how it works?  
 8 MS. DAVIDSON: Objection.

9 BY MR. SLATER:

10 Q. It's a yes-or-no question.  
 11 I just want to know if the same standards  
 12 apply to everybody.

13 MS. DAVIDSON: I don't know  
 14 if that's another question, but if  
 15 it is, I'm objecting to that one,  
 16 too.

17 THE WITNESS: So, again, I  
 18 do not understand the basis of  
 19 your question or your assumption  
 20 of ZHP knew that these were potent  
 21 and toxic impurities. ZHP did not  
 22 know that.

23 When ZHP found that, when  
 24 ZHP understood that they had NDMA,

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1 potential impurities that are  
 2 expected to be unusually potent,  
 3 for potential impurities that are  
 4 expected to be unusually potent.

5 If ZHP did not know that  
 6 that was a mutagenic impurity, how  
 7 would they conclude this is a  
 8 potent compound?

9 The same goes for the second  
 10 statement on Page 4, which says,  
 11 For impurities known to be  
 12 unusually potent or produce toxic  
 13 or unexpected effect.

14 Again, there is an  
 15 assumption in your questioning  
 16 that this unknown impurity was  
 17 potent.

18 BY MR. SLATER:

19 Q. Is the standard objective,  
 20 meaning we're going to hold all  
 21 manufacturers to a high standard, or is  
 22 it subjective, meaning, well, if this  
 23 manufacturer was really diligent and  
 24 figured out that there was a potential

1 they took all the right actions.

2 FDA didn't know in -- prior  
 3 to June 2018, prior to ZHP writing  
 4 to them and saying, hey, we have  
 5 NDMA present. FDA didn't know  
 6 that these unknown impurities in  
 7 valsartan which, according to FDA,  
 8 there were about 20 API  
 9 manufacturers, FDA didn't know  
 10 these were potent substances.

11 MR. SLATER: Let's go to the  
 12 next exhibit, which is the FDA  
 13 guidance for industry, Genotoxic  
 14 and Carcinogenic Impurities in  
 15 Drug Substances and Products,  
 16 Recommended Approaches, December  
 17 2008. Let's go to Exhibit-13.

18 - - -  
 19 (Whereupon, Exhibit  
 20 Afnan-13, No Bates, Guidance for  
 21 Industry Genotoxic and  
 22 Carcinogenic Impurities in Drug  
 23 Substances and Products:  
 24 Recommended Approaches, was marked

<p>1 for identification.)  2 - - -  3 BY MR. SLATER:  4 Q. Have you ever seen this  5 document?  6 A. It's a draft document. It's  7 a draft which then eventually -- so, yes,  8 I have.  9 Q. Are you aware that ZHP cited  10 to this document in its DMFs as being  11 applicable to the manufacturing processes  12 for valsartan?</p> <p>13 MS. DAVIDSON: Objection.  14 THE WITNESS: No, I'm not  15 aware that ZHP referenced this in  16 their DMF applications. I have  17 not come across that statement.</p> <p>18 BY MR. SLATER:  19 Q. Did you consider this  20 guidance for industry and its contents in  21 forming your opinions in this case?</p> <p>22 MS. DAVIDSON: Objection.  23 THE WITNESS: This is a  24 draft guidance, which is dated</p>	<p>Page 326</p> <p>1 2008.  2 In 2011, this was either  3 still a draft or not in process,  4 one.  5 As a draft guidance -- as a  6 fully approved guidance, if it was  7 an approved guidance, then it  8 would not be binding on FDA or  9 industry. That's stated on the  10 second or third page of every  11 guidance.</p> <p>12 BY MR. SLATER:  13 Q. Let's go to the  14 introduction, Page 1.  15 It says, This guidance is  16 intended to inform pharmaceutical  17 manufacturers of the Food and Drug  18 Administration's current thinking  19 regarding genotoxic and carcinogenic  20 impurities in drug substances and drug  21 products, including biologic products,  22 that are regulated by the Center For Drug  23 Evaluation and Research. This guidance  24 provides recommendations on how to</p>
<p>Page 327</p> <p>1 2008. It's an ICH guidance which  2 FDA had started working on, and,  3 therefore, it was in the various  4 stages.  5 This guidance later became a  6 final guidance.</p> <p>7 BY MR. SLATER:  8 Q. Did you consider this  9 guidance in forming your opinions, this  10 document; yes or no?</p> <p>11 MS. DAVIDSON: Objection.  12 THE WITNESS: I considered  13 --</p> <p>14 BY MR. SLATER:  15 Q. So you did not consider this  16 document, correct?</p> <p>17 A. This is a draft guidance  18 which is a precursor to M7.  19 Q. So is the answer, no, I did  20 not take this into account in forming my  21 opinions?</p> <p>22 MS. DAVIDSON: Objection.  23 THE WITNESS: This is a  24 draft guidance dating back to</p>	<p>Page 329</p> <p>1 evaluate the safety of these impurities  2 during clinical development,  3 investigational new drug applications and  4 for marketing applications, new drug  5 applications, NDAs, biologics, license  6 applications, BLAs and abbreviated new  7 drug applications, ANDAs.  8 Do you see what I just read?  9 A. Yes.  10 Q. Do you know if ZHP was aware  11 of this document and felt that it was  12 obligated to comply with it?  13 MS. DAVIDSON: Objection.  14 BY MR. SLATER:  15 Q. Even though it said it's  16 non-binding, do you know what ZHP's  17 position on that was?  18 MS. DAVIDSON: Objection.  19 When you say "this document," do  20 you mean the draft or the final?  21 MR. SLATER: Yes. It's the  22 only document on the screen.  23 BY MR. SLATER:  24 Q. Do you know what ZHP's</p>

<p>1 position was about this in their 2 depositions; yes or no? 3       A. It says, This draft 4 guidance, when finalized. It was not 5 final, one. 6       Two, taking into account the 7 same issue, if you look at the second 8 paragraph, it says, This guidance is 9 intended as an adjunct to the ICH 10 guidance for industry, Q3A. I -- 11      Q. Are you refusing to answer 12 my question? 13      MS. DAVIDSON: Please don't 14 interrupt him. 15      MR. SLATER: You know what, 16 Ms. Miller, I have to tell you 17 something, you have an obligation, 18 as an officer of the court, to 19 know that your witness is not 20 being responsive. This has gone 21 on all day. 22      I don't want to ask for more 23 time, but he has sucked hours out 24 of this deposition with these</p>	<p>Page 330</p> <p>1 have looked at development would have 2 looked at the development in a different 3 facility that I have not looked at, 4 number one. 5       Number two, whatever ZHP 6 developed was submitted both to EDQM and 7 to FDA. And both -- 8      Q. Go to the top of Page 2. 9      MS. DAVIDSON: I'm sorry, 10 Dr. Afnan, were you finished? 11      THE WITNESS: I said -- no, 12 I wasn't. 13      I said and both EDQ and FDA 14 accepted their application. 15 BY MR. SLATER: 16      Q. Look at the top of Page 2, 17 it says, This guidance describes a 18 variety of ways to characterize and 19 reduce the potential lifetime cancer risk 20 associated with patient exposure to 21 genotoxic and carcinogenic impurities, 22 both during clinical development and 23 after approval. 24      Do you see what I just read?</p> <p>Page 332</p>
<p>1 nonresponsive answers, objectively 2 speaking. And I think that it 3 would be in your interest as well, 4 to just say give him direct 5 answers to direct questions. 6       It would help all of us. 7 I'm not looking to come back 8 again. I would really like to 9 finish today. 10      But if the witness refuses 11 to answer simple questions, it's 12 very frustrating and it frustrates 13 the purpose of the deposition. 14 BY MR. SLATER: 15      Q. Do you know what ZHP's 16 position is as to whether the FDA 17 guidance that's on the screen applied to 18 its development and manufacture of 19 valsartan; yes or no? 20      A. I have not looked at 21 development reports from ZHP, so I cannot 22 make any comments about that. 23      This would have been 24 applicable -- or the group that would</p>	<p>Page 331</p> <p>1 A. Yes. 2      Q. These approaches include, 3 first bullet point, changing the 4 synthetic and/or purification routes to 5 minimize the formation and/or maximize 6 the removal of the relevant impurity. 7      Do you see that? 8      A. Yes. 9      Q. Number -- the second bullet 10 point, Allowing a maximum daily exposure 11 target of 1.5 micrograms per day for the 12 relevant impurity as a general target for 13 marketed products, though higher levels 14 may be acceptable during clinical 15 development. Certain impurities with 16 structural alerts, suggesting 17 particularly high genotoxic and 18 carcinogenic potential, would not be 19 appropriate for this general threshold 20 approach and would need to be evaluated 21 on a case-by-case basis. 22      Do you see what I just read? 23      A. Yes. 24      Q. N-nitroso compounds fall</p> <p>Page 333</p>

<p>Page 334</p> <p>1 within that category of impurities that 2 would not be appropriate for the 3 threshold approach, according to this 4 document; you understand that, correct?</p> <p>5 MS. DAVIDSON: Objection. 6 THE WITNESS: I do.</p> <p>7 However, at that time, 2008, 8 ZHP had no clue that their process 9 was making NDMA.</p> <p>10 BY MR. SLATER:</p> <p>11 Q. Let's go to the bottom of 12 the page where it says, Background.</p> <p>13 The compounds that have been 14 demonstrated to induce genetic mutations, 15 chromosomal breaks and/or chromosomal 16 rearrangements are considered genotoxic 17 and have the potential to cause cancer in 18 humans. Exposures to even low levels of 19 these impurities may be of significant 20 concern. Therefore, the identification 21 limits provided in ICH Q3A and ICH Q3B 22 may not be acceptable for genotoxic or 23 carcinogenic impurities.</p> <p>24 Do you see what I just read?</p>	<p>Page 336</p> <p>1 MS. DAVIDSON: Objection. 2 THE WITNESS: Yes.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. Let's go to Page 6. 5 Section 3 is titled, 6 Recommended Approaches for Initial 7 Assessment of Genotoxic Potential of 8 Impurities.</p> <p>9 Do you see that?</p> <p>10 A. I do.</p> <p>11 Q. The third paragraph under 12 that says, If an impurity that is present 13 at levels below the ICH qualification 14 thresholds is identified, the impurity 15 should be evaluated for genotoxicity and 16 carcinogenicity based on structural 17 activity relationship assessments, i.e., 18 whether there is a structural alert. 19 This evaluation can be conducted via 20 review of the available literature or 21 through a computational toxicology 22 assessment. Commonly used software 23 includes -- and they give examples of the 24 software.</p>
<p>Page 335</p> <p>1 A. Yes.</p> <p>2 Q. Going a little further down, 3 about four lines further down, it says, 4 Although genotoxic and carcinogenic 5 properties can be acceptable for some 6 active pharmaceutical ingredients, APIs, 7 depending on clinical circumstances, for 8 example, cancer chemotherapies, 9 impurities in drug substances and drug 10 products generally do not have beneficial 11 effects and may impose a risk without 12 associated benefit. Therefore, 13 manufacturers should strive to achieve 14 the lowest levels of genotoxic or 15 carcinogenic impurities that are 16 technically feasible and/or levels that 17 convey no significant cancer risk.</p> <p>18 Do you see what I just read?</p> <p>19 A. Yes.</p> <p>20 Q. And, again, the types of 21 impurities we're talking about would 22 include N-nitroso compounds, and that's 23 what they're talking about in this 24 guidance in 2008, correct?</p>	<p>Page 337</p> <p>1 Do you see what I just read?</p> <p>2 A. Yes.</p> <p>3 Q. And, again, if the impurity, 4 in this case NDMA from the zinc chloride 5 process, had been evaluated, it would 6 have been identified as NDMA and then ZHP 7 would have been duty bound to take action 8 to eliminate it from the valsartan and 9 not sell the valsartan with the NDMA, 10 correct?</p> <p>11 MS. DAVIDSON: Objection.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. I don't know what's so 14 funny, Doctor.</p> <p>15 Can you just answer that 16 with a yes or no, please?</p> <p>17 A. No, I can't answer with a 18 yes or no.</p> <p>19 MS. DAVIDSON: Objection.</p> <p>20 BY MR. SLATER:</p> <p>21 Q. Fine. You can't answer with 22 a yes or no, I'll move to the next 23 question.</p> <p>24 Let's go to Page 7.</p>

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1           Section 4 is titled,  
 2 Recommended Approaches for Handling  
 3 Genotoxic and Carcinogenic Impurities.  
 4           And then Section A under  
 5 that is titled, Prevention of Genotoxic  
 6 and Carcinogenic Impurity Formation.  
 7           Do you see that?

8           A. Yes.

9           Q. Prevention of genotoxic and  
 10 carcinogenic impurity formation is  
 11 important in drug manufacturing, correct?

12          A. Yes.

13          Q. You always want to prevent  
 14 the formation of genotoxic and  
 15 carcinogenic impurities when you're  
 16 manufacturing drug substances, correct?

17          MS. DAVIDSON: Objection.

18          THE WITNESS: So, again,  
 19 this guidance -- this draft  
 20 guidance, which was published in  
 21 2008, ZHP's process in 2007 was  
 22 actually the TIN process.

23          ZHP's process was  
 24 investigated when they changed to

1           the presence of these mutagenic  
 2 substances.

3 BY MR. SLATER:

4           Q. Look now --

5           MS. DAVIDSON: Can we --

6           MR. SLATER: I'm right in  
 7 the middle of this document. I'm  
 8 not breaking while I'm going  
 9 through this document. I'm sorry.

10 BY MR. SLATER:

11          Q. Looking now at Section A, it  
 12 says, under the heading of, Prevention of  
 13 Genotoxic and Carcinogenic Impurity  
 14 Formation, Since drug-related impurities  
 15 presumably provide limited, if any,  
 16 therapeutic benefits and because of their  
 17 potential to cause cancer in humans,  
 18 every feasible technical effort should be  
 19 made to prevent the formation of  
 20 genotoxic or carcinogenic compounds  
 21 during drug substance synthesis or drug  
 22 product manufacturing.

23          Do you see that?

24          A. Yes.

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1           the TEA and also when they changed  
 2 to the zinc chloride process.

3           And they looked, they  
 4 assessed whether genotoxic  
 5 impurities would be formed and  
 6 they concluded that they're not  
 7 present.

8           They were going from an  
 9 existing process, which was the  
 10 TIN process, to the TEA process  
 11 and then to the zinc chloride  
 12 process. So what you're reading  
 13 to me out of this draft guidance  
 14 dated 2008 has an assumption that  
 15 if a manufacturer knew that it  
 16 has, effectively, carcinogenic  
 17 substances in it, would they have  
 18 an obligation to do what you say  
 19 here? The answer is yes.

20          However, ZHP investigated,  
 21 assessed and decided that it  
 22 didn't know. FDA vouches for that  
 23 when FDA says, FDA nor industry  
 24 knew about the formation, about

1           Q. Do you see what I just read?

2          A. I do.

3          Q. And you agree that ZHP  
 4 needed to make every feasible technical  
 5 effort to prevent the formation of  
 6 genotoxic or carcinogenic compounds  
 7 during the synthesis and manufacture of  
 8 the valsartan it manufactured, correct?

9           MS. DAVIDSON: Objection.

10          THE WITNESS: If ZHP knew of  
 11 the formation of genotoxic  
 12 compounds, yes.

13          This is not the case here.

14          ZHP did not know about the  
 15 formation of NDMA or NDEA in its  
 16 valsartan process.

17 BY MR. SLATER:

18          Q. Let's flip over to the next  
 19 page.

20          MR. SLATER: Actually, no,  
 21 no. Let's scroll down. Scroll  
 22 down.

23 BY MR. SLATER:

24          Q. Do you see at the bottom of

<p style="text-align: right;">Page 342</p> <p><sup>1</sup> the page it says, under B1, the title is,  <sup>2</sup> Acceptable Levels to Support Marketing  <sup>3</sup> Applications.</p> <p><sup>4</sup> Do you see that?</p> <p><sup>5</sup> A. Yes.</p> <p><sup>6</sup> Q. And that's the thresholds  <sup>7</sup> that you've been talking about during the  <sup>8</sup> deposition, right?</p> <p><sup>9</sup> A. The threshold --</p> <p><sup>10</sup> MS. DAVIDSON: Objection.</p> <p><sup>11</sup> THE WITNESS: No. The  <sup>12</sup> threshold is based on, actually --  <sup>13</sup> this is the threshold for -- in  <sup>14</sup> this guidance, for very specific  <sup>15</sup> substances. The threshold is what  <sup>16</sup> is effectively detectable.</p> <p><sup>17</sup> So we're looking at two  <sup>18</sup> different things.</p> <p><sup>19</sup> You are making an assumption  <sup>20</sup> that every impurity is genotoxic  <sup>21</sup> in ZHP process and in ZHP product.  <sup>22</sup> That's not the case.</p> <p><sup>23</sup> ZHP assessed the process.  <sup>24</sup> ZHP shared that assessment with</p>	<p style="text-align: right;">Page 344</p> <p><sup>1</sup> BY MR. SLATER:</p> <p><sup>2</sup> Q. Fine.</p> <p><sup>3</sup> A. FDA --</p> <p><sup>4</sup> Q. You said they didn't do it.</p> <p><sup>5</sup> Doctor, you answered my question.</p> <p><sup>6</sup> MS. DAVIDSON: No, no, Adam.</p> <p><sup>7</sup> If he has something to finish, you  <sup>8</sup> know that -- when you've had  <sup>9</sup> witnesses, you have them finish  <sup>10</sup> their answers, including  <sup>11</sup> Dr. Plunkett, who had very long  <sup>12</sup> answers.</p> <p><sup>13</sup> Dr. Afnan, complete your  <sup>14</sup> answer.</p> <p><sup>15</sup> THE WITNESS: FDA --</p> <p><sup>16</sup> MR. SLATER: Again, let me  <sup>17</sup> say for the record, you're telling  <sup>18</sup> your witness to ramble on  <sup>19</sup> non-responsively to keep sucking  <sup>20</sup> time out of the deposition, as an  <sup>21</sup> officer of the court.</p> <p><sup>22</sup> MS. DAVIDSON: No, that's  <sup>23</sup> not what I'm telling the witness.  <sup>24</sup> He's not my witness, first of all.</p>
<p style="text-align: right;">Page 343</p> <p><sup>1</sup> the regulators, that I do not have  <sup>2</sup> any mutagenic substances. ZHP  <sup>3</sup> received approval from the  <sup>4</sup> regulators that there were no  <sup>5</sup> mutagenic substances. FDA bears  <sup>6</sup> testimony, publicly, by saying  <sup>7</sup> neither the regulator nor the  <sup>8</sup> manufacturers knew about the  <sup>9</sup> formation of NDMA nor about -- it  <sup>10</sup> calls them unexpected impurities.</p> <p><sup>11</sup> BY MR. SLATER:</p> <p><sup>12</sup> Q. And they issued a warning  <sup>13</sup> letter to ZHP -- and when they made all  <sup>14</sup> those statements that you just told me,  <sup>15</sup> in the statement from the FDA, they  <sup>16</sup> pointed out that they issued a warning  <sup>17</sup> letter to ZHP for its GMP violations that  <sup>18</sup> allowed these substances to exist in its  <sup>19</sup> valsartan; that's also what the FDA did,  <sup>20</sup> correct?</p> <p><sup>21</sup> MS. DAVIDSON: Objection.  <sup>22</sup> Misstates many, many things.</p> <p><sup>23</sup> THE WITNESS: No. FDA  <sup>24</sup> didn't do that.</p>	<p style="text-align: right;">Page 345</p> <p><sup>1</sup> He's an expert witness.</p> <p><sup>2</sup> MR. SLATER: Let him answer.</p> <p><sup>3</sup> Do you want --</p> <p><sup>4</sup> MS. DAVIDSON: He's in the  <sup>5</sup> middle of answering a question.  <sup>6</sup> You can't just cut him off, Adam,  <sup>7</sup> you know that. You know better  <sup>8</sup> than that.</p> <p><sup>9</sup> MR. SLATER: Thank you. I  <sup>10</sup> know better? You stand behind  <sup>11</sup> what's going on in this  <sup>12</sup> deposition? I find that hard to  <sup>13</sup> imagine, but I guess you do.</p> <p><sup>14</sup> BY MR. SLATER:</p> <p><sup>15</sup> Q. Do you have something else  <sup>16</sup> you want to say, Doctor, in response to  <sup>17</sup> my last question?</p> <p><sup>18</sup> A. Yes, I do.</p> <p><sup>19</sup> MS. DAVIDSON: He was in the  <sup>20</sup> middle of the answer.</p> <p><sup>21</sup> THE WITNESS: Yes, I do.</p> <p><sup>22</sup> MS. DAVIDSON: Do you even  <sup>23</sup> recall what you were talking  <sup>24</sup> about? Because I don't.</p>

1           MR. SLATER: Why are you  
2 saying that to him? Why would you  
3 suggest to him to say he doesn't  
4 remember? Why would you do that?  
5 It's inappropriate.

6           MS. DAVIDSON: I'm asking if  
7 he wants the question read back,  
8 Adam, because --

9           MR. SLATER: He doesn't  
10 need --

11          MS. DAVIDSON: -- all of  
12 your explosions make it impossible  
13 for me to even know where we were.  
14 Because you rudely interrupted  
15 him, then attacked me and then  
16 attacked the witness.

17          If he can -- if he  
18 remembers, great. I don't.

19          Go ahead, Dr. Afnan.

20          THE WITNESS: ZHP was issued  
21 a warning letter. The warning  
22 letter which effectively, as I  
23 have said, is informal and  
24 advisory, as per FDA. And that

1           been making NDMA in its process  
2 since 2007 or '10 or '11 or  
3 whatever. It's not there.

4           MS. DAVIDSON: All right.  
5 Are we ready for a break? I think  
6 everybody needs a break.

7           MR. SLATER: No, I'm not  
8 done with this document, and I'm  
9 not breaking.

10          MS. DAVIDSON: I'm not  
11 familiar with the rule that you  
12 can go on with a document forever  
13 to prevent people from taking a  
14 break and going to the bathroom.

15          THE WITNESS: I am ready for  
16 a break.

17          MR. SLATER: You guys, if  
18 you want to stop, even though I'm  
19 asking you not to stop, I can't  
20 physically stop you.

21          So you tell me what you want  
22 to do. I'd like to continue. If  
23 you want to make me stop --

24          MS. DAVIDSON: Do you -- I

1           was issued because FDA needed more  
2 information on the conclusion of  
3 the investigation.

4           If you look at the  
5 communications after the warning  
6 letter between FDA and ZHP, FDA is  
7 as interested in the outcome of  
8 the warning letter -- of the  
9 investigation into the formation  
10 of NDMA as is ZHP.

11          By that time, if -- you  
12 know, there is no product being  
13 manufactured, the process is  
14 changed -- or the process  
15 had stopped and the process was  
16 changed later.

17          So the warning letter is  
18 there as an informal iterative  
19 action by FDA to actually move the  
20 firm to come up with a conclusion  
21 of what the pathway for formation  
22 of these substances are.

23          FDA, at no point, states in  
24 the warning letter that ZHP has

1           would like to be cooperative.

2           Do you have more than five  
3 minutes left on this document?

4           MR. SLATER: I don't know,  
5 because every question I ask, I  
6 get a long, rambling nonresponsive  
7 speech. So I would say, yes, less  
8 than five minutes if I get  
9 responsive answers to questions.

10          MS. DAVIDSON: Adam, that's  
11 not necessary. If you have more  
12 than five --

13          MR. SLATER: Yes, it is.

14          MS. DAVIDSON: If you have  
15 more than five minutes on the  
16 document, I think we should take a  
17 break.

18          MR. SLATER: I don't. I  
19 don't have more than five minutes.

20          You just asked me. I don't  
21 have more than five minutes on the  
22 document. You can ask the expert  
23 that you hired whether or not he  
24 could answer questions with a

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1 direct answer. You're wasting my  
 2 time on this video.

3 MS. DAVIDSON: You're  
 4 wasting it. So let's --

5 MR. SLATER: What do you  
 6 want to do, break or not break?

7 Make a decision, please.

8 MS. DAVIDSON: I would like  
 9 to have a break and go to the  
 10 ladies room.

11 THE WITNESS: Yes, please.

12 MR. SLATER: Off the record.

13 VIDEO TECHNICIAN: We're off  
 14 the record at 5:02 p.m.  
 15 - - -

16 (Whereupon, a brief recess  
 17 was taken.)  
 18 - - -

19 VIDEO TECHNICIAN: We're  
 20 back on the record at 5:07 p.m.

21 BY MR. SLATER:

22 Q. Looking at --

23 MR. SLATER: Where is the  
 24 document?

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1 BY MR. SLATER:

2 Q. Looking at Section B1,  
 3 titled, Acceptable Levels to Support  
 4 Marketing Applications. Let's go to the  
 5 carryover of that paragraph on the top of  
 6 Page 8.

7 And after they talk about  
 8 various threshold levels, they state, at  
 9 the end of that paragraph, at the top of  
 10 the page, However, there are some  
 11 compounds containing certain structural  
 12 groups, aflatoxin-like, N-nitroso and  
 13 azoxy structures, that have extremely  
 14 high carcinogenic potency and are  
 15 excluded from the threshold approach.

16 Do you see that?

17 A. Yes.

18 Q. That includes NDMA and NDEA,  
 19 correct?

20 A. Yes.

21 Q. So if FDA, in its guidance  
 22 in 2008, said NDMA and NDEA are excluded  
 23 from the threshold approach; that's what  
 24 that means, correct?

1 A. Yes.

2 Q. Let's go to Page 13.

3 Appendix A to this document  
 4 is the decision tree flow diagram.

5 Do you see that?

6 A. Yes.

7 Q. At the very top it says,  
 8 Identify impurity.

9 Do you see that?

10 A. Yes.

11 Q. That's the first thing the  
 12 manufacturer is supposed to do, is  
 13 actually make every feasible technical  
 14 effort, as I read that language from  
 15 earlier in the document, to identify the  
 16 impurity, right?

17 MS. DAVIDSON: Objection.

18 THE WITNESS: Only if the  
 19 expectation is for the impurity to  
 20 be genotoxic.

21 BY MR. SLATER:

22 Q. It says, Once you identify  
 23 the impurity, observed level exceeds --  
 24 let me go back, actually, to what you

1 just said.

2 You're saying that you have  
 3 to know that you have a genotoxic  
 4 impurity before you have to look for the  
 5 impurity and identify it?

6 Isn't that a little  
 7 circular, Doctor?

8 MS. DAVIDSON: Objection.

9 THE WITNESS: I don't think  
 10 it is. I think what the  
 11 requirements are, there has to be  
 12 an expectation of genotoxic  
 13 impurities; an expectation of  
 14 genotoxic impurities.

15 BY MR. SLATER:

16 Q. What if you have an  
 17 understanding of potential formation of  
 18 genotoxic impurities, you don't expect it  
 19 to be formed, but you know it might form  
 20 from the process that you -- that you're  
 21 using, are you able to say, well, we  
 22 don't expect it, so we're not going to  
 23 investigate why it's there, whether it's  
 24 there or not? Is that acceptable?

1 MS. DAVIDSON: Objection.

2 MR. SLATER: Let me ask it  
3 again.

4 BY MR. SLATER:

5 Q. You say if it's expected.

6 What if it's known to be  
7 possible, based on an understanding of  
8 the chemical process at issue? In that  
9 case, are you allowed to ignore  
10 identification of the impurity because  
11 you don't know for sure that it's been  
12 formed, or do you have to actually  
13 investigate to see if it's there?

14 MS. DAVIDSON: Same  
15 objections.

16 THE WITNESS: The answer is,  
17 if you expect it to be there, you  
18 need to identify it.

19 In this case, ZHP did not  
20 know that it was potentially there  
21 or it could potentially be formed.

22 BY MR. SLATER:

23 Q. If ZHP knew that it could  
24 potentially form, they would have been

1 And, again, that's not what  
2 the case is here. ZHP didn't expect it  
3 nor did it know potentially it would be  
4 there.

5 Q. Looking at the decision  
6 tree, this says, once you identify the  
7 impurity, you go to the next question,  
8 Whether the observed level exceeds the  
9 relevant ICH qualification threshold or  
10 is less than ICH qualification threshold  
11 but displays a structural alert.

12 Do you see that?

13 A. Yes.

14 Q. So that's telling you, if  
15 you identified NDMA or NDEA, even if it  
16 was in a quantity less than the ICH  
17 qualification threshold, you would then  
18 have to go down where it says, yes, and  
19 determine, Are you able to prevent the  
20 formation of the impurity, correct?

21 A. Yes. And, again, not the  
22 case here.

23 Q. It's not the case here  
24 because ZHP did not evaluate the

1 required to test for the NDMA and NDEA,  
2 correct?

3 A. If they expected it to be  
4 there, yes. But they did not know. This  
5 is not the case here.

6 Q. Why do you keep changing my  
7 question? I did not ask about if they  
8 expected it.

9 In fact, you didn't answer  
10 my prior question, Doctor, you evaded it.

11 What you said -- I asked you  
12 a question, and I'll try it again.

13 A. Okay.

14 Q. If ZHP didn't expect NDMA to  
15 form but knew that it was potentially  
16 going to form based on an understanding  
17 of the chemical reactions, did ZHP have  
18 to test to see if NDMA was forming?

19 A. It didn't expect it but  
20 potentially knew it would be there? To  
21 me, both those two are the same.

22 If you expect it to be there  
23 or if you believe, potentially, it is  
24 going to be there, you will test for it.

1 potential formation -- well, rephrase.

2 It's not the case here

3 because ZHP did not identify the  
4 potential for the formation of  
5 nitrosamines in its manufacturing  
6 process, correct? That's your opinion,  
7 right?

8 A. Yes. ZHP looked at the  
9 process and did not predict or estimate  
10 or come up with a reason, justification  
11 for formation of mutagenic substances.

12 Q. And the basis of your  
13 opinion that ZHP was not expected to  
14 identify the potential formation of NDMA  
15 or NDEA in these processes is your  
16 reliance on Dr. Xue for that point,  
17 correct?

18 A. No, no, no.

19 MS. DAVIDSON: Objection.

20 BY MR. SLATER:

21 Q. So you're now an organic  
22 chemistry expert again?

23 A. No, no. I haven't answered  
24 yet.

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1 MS. DAVIDSON: And I haven't  
2 even had a chance to -- to object,  
3 because everybody is talking over  
4 each other.

5 I object to that question.  
6 It mischaracterizes his testimony.

7 Also, he started answering,  
8 you did not let him finish. And  
9 you, again, made a sarcastic  
10 retort. Let him answer the  
11 question.

12 THE WITNESS: I am not an  
13 organic chemist. I am not  
14 responding as an organic chemist,  
15 I am not relying solely on  
16 Dr. Xue's expertise in this case.

17 I am looking at what was  
18 developed in the early phases in  
19 2010, 2012, 2013, and submitted to  
20 the regulators for their review  
21 and approval. They did not  
22 identify mutagenic substances  
23 prior to 2018.

24 BY MR. SLATER:

1 organic chemistry, in terms of an  
2 understanding of the literature and what  
3 was available out there and what could  
4 have been found and identified by organic  
5 chemists, correct?

6 A. Your question had the word  
7 "expected to." My response has been and  
8 continues to be that ZHP looked at the  
9 process and they came to the conclusion  
10 that there are no mutagenic substances  
11 formed in the process.

12 Furthermore, this was a  
13 change to the TIN process, which went  
14 from TIN to TEA and then it went to zinc  
15 chloride. The time difference between  
16 the TIN and the zinc chloride process was  
17 three years.

18 There was a lot of studies  
19 done during that time period, as well as  
20 when they changed to TEA. So they did  
21 investigate. They didn't see, they  
22 didn't predict -- they didn't predict,  
23 they didn't estimate, they did not come  
24 up with that expectation of, oh, NDMA

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1 Q. For your opinion that the  
2 organic chemists at ZHP were not expected  
3 to figure out that there was a potential  
4 for the formation of NDMA or NDEA, do you  
5 rely on Dr. Xue's opinion that it would  
6 not be expected for a chemist to have  
7 known or figured that out, or do you have  
8 the opinion that the organic chemist did  
9 not need to figure that out?

10 I'm trying to figure out  
11 where your basis is to give this organic  
12 chemistry opinion.

13 MS. DAVIDSON: Objection.  
14 If that's a question.

15 THE WITNESS: I'm not --

16 BY MR. SLATER:

17 Q. I'll ask it differently,  
18 Doctor.

19 A. No, I --

20 Q. The question of whether --  
21 the question of whether ZHP's chemists  
22 were expected to identify the potential  
23 formation of nitrosamines in these  
24 manufacturing processes is a question of

1 will be formed here.

2 FDA also looked at the same  
3 data, the same information, and the same  
4 chemistry, and did not come up with a  
5 conclusion of mutagenic substances are  
6 formed in this process.

7 Q. Is that the basis for your  
8 opinion that ZHP was not expected to  
9 identify the potential formation of  
10 nitrosamines?

11 What you just went through,  
12 is that -- I'm just asking you, is that  
13 the basis for the opinion?

14 MS. DAVIDSON: Objection.

15 BY MR. SLATER:

16 Q. I don't need you to repeat  
17 it.

18 I just need to know, is that  
19 the basis for the opinion?

20 A. That was not the opinion I  
21 expressed.

22 Q. One of the reasons why you  
23 say ZHP was not expected to identify the  
24 potential formation of nitrosamines is

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<sup>1</sup> because ZHP did not identify the  
<sup>2</sup> potential formation of the nitrosamines  
<sup>3</sup> based on their risk assessment; is that  
<sup>4</sup> one of the reasons why you give that  
<sup>5</sup> opinion, because they didn't figure it  
<sup>6</sup> out?

<sup>7</sup> A. It's based on the risk  
<sup>8</sup> assessment, as well as the research they  
<sup>9</sup> have done.

<sup>10</sup> Q. Another basis for your  
<sup>11</sup> opinion is that the FDA didn't identify  
<sup>12</sup> that risk of formation of nitrosamines.  
<sup>13</sup> That's another reason why you say ZHP was  
<sup>14</sup> not expected to identify that potential  
<sup>15</sup> risk.

<sup>16</sup> Do I understand that  
<sup>17</sup> correctly?

<sup>18</sup> A. I'm not using the FDA  
<sup>19</sup> statement as a reason of saying that's  
<sup>20</sup> because they didn't find it.

<sup>21</sup> I'm saying, the FDA's  
<sup>22</sup> statement verifies that they did not find  
<sup>23</sup> it, they did not have an expectation of  
<sup>24</sup> doing so.

<sup>1</sup> The original process was  
<sup>2</sup> developed in 2007. Then, as they changed  
<sup>3</sup> each step, they looked at the potentials  
<sup>4</sup> of, you know, formation of undesired  
<sup>5</sup> impurities, and their conclusion was that  
<sup>6</sup> there is nothing there.

<sup>7</sup> The analytical data  
<sup>8</sup> supported that they were not finding  
<sup>9</sup> anything or that there was no NDMA  
<sup>10</sup> present.

<sup>11</sup> Q. In forming the opinion --  
<sup>12</sup> well, rephrase.

<sup>13</sup> I don't need to go over it  
<sup>14</sup> again.

<sup>15</sup> MR. SLATER: Let's take this  
<sup>16</sup> document down. And let's go to --  
<sup>17</sup> back to the warning letter, okay.

<sup>18</sup> I'm going to go back to the  
<sup>19</sup> FDA warning letter. I think we  
<sup>20</sup> used it. Yeah. We used it very  
<sup>21</sup> early on.

<sup>22</sup> THE WITNESS: Yes, we did.

<sup>23</sup> MR. SLATER: It was  
<sup>24</sup> Exhibit-2 or 3 or something?

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<sup>1</sup> I'm not saying that ZHP  
<sup>2</sup> based their decision on what the FDA had  
<sup>3</sup> said, because the FDA said this in 2018.  
<sup>4</sup> I'm saying the statements, two of, in  
<sup>5</sup> 2018 and 2019, were effectively verifying  
<sup>6</sup> that ZHP had not looked at the process  
<sup>7</sup> and said, you know, we expect NDMA. FDA  
<sup>8</sup> says, it was not expected to be there.

<sup>9</sup> Q. In terms of your  
<sup>10</sup> understanding that ZHP was not expected  
<sup>11</sup> to have been able to identify the  
<sup>12</sup> potential formation of nitrosamines, is  
<sup>13</sup> there anything else that you're relying  
<sup>14</sup> on besides what you just told me, those  
<sup>15</sup> two points, for that opinion?

<sup>16</sup> A. It's the investigation,  
<sup>17</sup> which they had done, the assessments that  
<sup>18</sup> they had done, the reports that they had  
<sup>19</sup> issued, which effectively said, we've  
<sup>20</sup> looked at the process and we do not  
<sup>21</sup> expect any carcinogenic impurities.

<sup>22</sup> The process -- this was a  
<sup>23</sup> process revision, this was a process  
<sup>24</sup> update -- or a process change.

<sup>1</sup> MS. DAVIDSON: Yeah, let's  
<sup>2</sup> just make sure for the record we  
<sup>3</sup> identify what the exhibit number  
<sup>4</sup> is.

<sup>5</sup> MR. SLATER: Exhibit-4.

<sup>6</sup> MS. DAVIDSON: Thanks.

<sup>7</sup> BY MR. SLATER:

<sup>8</sup> Q. Let's go, in the warning  
<sup>9</sup> letter, to Page 4.

<sup>10</sup> This is what the FDA said in  
<sup>11</sup> Section 2, the heading is, Failure to  
<sup>12</sup> Evaluate the Potential Effect That  
<sup>13</sup> Changes in the Manufacturing Process May  
<sup>14</sup> Have on the Quality of Your API.

<sup>15</sup> Do you see that heading?

<sup>16</sup> A. Yes.

<sup>17</sup> Q. The FDA states, In November  
<sup>18</sup> 2011, you approved the valsartan API  
<sup>19</sup> process change that included the use of  
<sup>20</sup> the solvent DMF. Your intention was to  
<sup>21</sup> improve the manufacturing process,  
<sup>22</sup> increase product yield and lower  
<sup>23</sup> production costs. However, you failed to  
<sup>24</sup> adequately assess the potential formation

<p>1 of mutagenic impurities when you      2 implemented the new process.      3 Specifically, you did not consider the      4 potential for mutagenic or other toxic      5 impurities to form from DMF degradants,      6 including the primary DMF degradant      7 dimethylamine. According to your ongoing      8 investigation, dimethylamine is required      9 for the probable human carcinogen NDMA to      10 form during the valsartan API      11 manufacturing process. NDMA was      12 identified in valsartan API manufactured      13 at your facility.</p> <p>14 Do you see what I just read?</p> <p>15 A. Yes.</p> <p>16 Q. So you agree the FDA found a      17 violation of cGMP based on the failure to      18 adequately assess the potential formation      19 of mutagenic impurities when they      20 implemented the new process.</p> <p>21 That's what it says on the      22 document, correct?</p> <p>23 A. That's what it says on the      24 document, which is written and issued</p>	<p>Page 366</p> <p>1 page say, correct?      2 MS. DAVIDSON: Objection.      3 Mischaracterizes the document.      4 BY MR. SLATER:      5 Q. It's what it says, right,      6 Doctor?      7 A. It says, You failed to      8 evaluate the need for analytical -- for      9 additional analytical methods.      10 Again, it's important to      11 look at the warning letter in the light      12 of events that took place. When ZHP      13 identified presence of NDMA, ZHP took      14 action. They stopped manufacturing.      15 They started investigating. They      16 informed the FDA. They did a recall.      17 They did all of those.      18 So this, which is issued in      19 November of 2018, is actually there to      20 make sure that ZHP is going to keep its      21 end of the bargain and continue its      22 investigation.      23 Otherwise, ZHP had stopped      24 production, had stopped shipping, even</p>
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<p>Page 367</p> <p>1 with the benefit of hindsight.</p> <p>2 Q. The next paragraph says, You      3 also failed to evaluate the need for      4 additional analytical methods to ensure      5 that unanticipated impurities were      6 appropriately detected and controlled in      7 your valsartan API before you approved      8 the process change. You are responsible      9 for developing and using suitable methods      10 to detect impurities when developing and      11 making change to your manufacturing      12 processes. If new or higher levels of      13 impurities are detected, you should fully      14 evaluate the impurities and take action      15 to ensure the drug is safe for patients.</p> <p>16 Do you see what I just read?</p> <p>17 A. Yes.</p> <p>18 Q. So the FDA found, again, a      19 violation of cGMP because ZHP failed to      20 apply analytical methods sufficient to      21 identify these new impurities, and      22 specifically NDMA -- NDMA and NDEA in      23 their valsartan.</p> <p>24 That's what the words on the</p>	<p>Page 369</p> <p>1 before the import letter was put in      2 place.</p> <p>3 Q. Going now to the third      4 paragraph, the FDA states, Your response      5 states that predicting NDMA formation      6 during the valsartan manufacturing      7 process required an extra dimension over      8 current industry practice and that your      9 process development study was adequate.      10 We disagree. We remind you that common      11 industry practice may not always be      12 consistent with cGMP requirements and      13 that you are responsible for the quality      14 of drugs you produce.</p> <p>15 Do you see what I just read?</p> <p>16 A. Yes.</p> <p>17 Q. Did you read that when you      18 wrote your opinion in your report?</p> <p>19 MS. DAVIDSON: Objection.      20 THE WITNESS: Yes.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. You keep saying to me, for      23 the last however many hours we've been in      24 this deposition, well, the FDA didn't</p>
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<sup>1</sup> find it, so there was no obligation for  
<sup>2</sup> ZHP to find it.

<sup>3</sup> This warning letter from the  
<sup>4</sup> FDA tells ZHP that it was their  
<sup>5</sup> responsibility to identify the NDMA and  
<sup>6</sup> they failed to do so.

<sup>7</sup> That's what the words on the  
<sup>8</sup> page say, correct?

<sup>9</sup> A. Again, those are the words  
<sup>10</sup> on the page. But it has to be taken in  
<sup>11</sup> the context of what's going on. FDA had  
<sup>12</sup> received, had shared every document that  
<sup>13</sup> ZHP did. Every process that ZHP  
<sup>14</sup> developed was shared with FDA. It was  
<sup>15</sup> shared through the amendments to the DMF.  
<sup>16</sup> It was also informed to FDA when the  
<sup>17</sup> ANDAs were filed with FDA.

<sup>18</sup> So all of those were shared  
<sup>19</sup> with FDA. This is in the -- with 20/20  
<sup>20</sup> hindsight, in November of 2018, after FDA  
<sup>21</sup> has been to site multiple times, has not  
<sup>22</sup> found any issues with the quality system.  
<sup>23</sup> Then a for-cause inspection, which  
<sup>24</sup> results in this warning letter.

<sup>1</sup> inspection and after review of  
<sup>2</sup> their response to the inspection.

<sup>3</sup> BY MR. SLATER:

<sup>4</sup> Q. Is it your -- rephrase.

<sup>5</sup> In forming your opinions,  
<sup>6</sup> did you discount the significance of the  
<sup>7</sup> retrospective analysis of what occurred,  
<sup>8</sup> including that performed by ZHP and that  
<sup>9</sup> performed by the FDA, because it was  
<sup>10</sup> being done in hindsight?

<sup>11</sup> A. Sorry. Could you either  
<sup>12</sup> rephrase or explain that question to me  
<sup>13</sup> again?

<sup>14</sup> Q. Sure.

<sup>15</sup> In forming your opinions as  
<sup>16</sup> to whether or not ZHP complied with  
<sup>17</sup> cGMPs --

<sup>18</sup> A. Yes.

<sup>19</sup> Q. -- did you discount the  
<sup>20</sup> significance of the FDA's findings in  
<sup>21</sup> this warning letter and discount the  
<sup>22</sup> significance of the findings by ZHP in  
<sup>23</sup> its own deviation investigation reports  
<sup>24</sup> because they were hindsight analyses

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<sup>1</sup> So it has to be taken in the  
<sup>2</sup> light of where it is, you know. It's --  
<sup>3</sup> it's suddenly ZHP goes from being  
<sup>4</sup> compliant to noncompliant on 29th of  
<sup>5</sup> November 2018.

<sup>6</sup> Q. One of the things you've  
<sup>7</sup> said to me multiple times is, well, this  
<sup>8</sup> is with the benefit of hindsight, this is  
<sup>9</sup> looking back with hindsight.

<sup>10</sup> You'd said that a few times  
<sup>11</sup> to me, right?

<sup>12</sup> A. Yes.

<sup>13</sup> Q. Does the FDA have a warning  
<sup>14</sup> letter that they also will issue in a  
<sup>15</sup> different circumstance where they look  
<sup>16</sup> into their crystal ball and see what  
<sup>17</sup> someone is going to do in the future and  
<sup>18</sup> give them a warning letter for future  
<sup>19</sup> conduct that hasn't happened yet? Is  
<sup>20</sup> there the crystal ball warning letter  
<sup>21</sup> also?

<sup>22</sup> MS. DAVIDSON: Objection.

<sup>23</sup> THE WITNESS: Warning  
<sup>24</sup> letters are issued after an

<sup>1</sup> looking back on what happened?

<sup>2</sup> MS. DAVIDSON: Objection.

<sup>3</sup> BY MR. SLATER:

<sup>4</sup> Q. I just want to know, yes or  
<sup>5</sup> no, did you do that?

<sup>6</sup> MS. DAVIDSON: Okay. Again,  
<sup>7</sup> every single time you ask a  
<sup>8</sup> question I object and then you  
<sup>9</sup> have your little colloquy.

<sup>10</sup> I'm objecting to the  
<sup>11</sup> question, and if that follow up is  
<sup>12</sup> a question, to that as well.

<sup>13</sup> THE WITNESS: So, again, you  
<sup>14</sup> know, in June of 2018, when ZHP  
<sup>15</sup> informed FDA about presence of  
<sup>16</sup> NDMA, FDA did not issue,  
<sup>17</sup> immediately, a warning letter and  
<sup>18</sup> say, you know what, you're done,  
<sup>19</sup> this is it, go back.

<sup>20</sup> FDA's warning letter is  
<sup>21</sup> issued after the response. FDA  
<sup>22</sup> issues this warning letter because  
<sup>23</sup> the response was not as expected,  
<sup>24</sup> the response to the 483.

1           MR. SLATER: We're now going  
 2 to put up on the screen  
 3 Exhibit-14.  
 4           - - -

5           (Whereupon, Exhibit  
 6 Afnan-14, ZHP00662283-2309,  
 7 Investigation Regarding an Unknown  
 8 Impurity (Genotoxic Impurity), was  
 9 marked for identification.)  
 10          - - -

11 BY MR. SLATER:

12 Q. This is a draft of the  
 13 deviation investigation report, draft of  
 14 Version 1.

15          Do you see this on the  
 16 screen? Have you seen this document  
 17 before?

18          A. I have seen the final  
 19 version, yes.

20          Q. All right. Well, let me go  
 21 to -- let's go to -- the Bates number is  
 22 308 at the bottom right.

23          A. 308.

24          Q. Under Section 5.2, it says,

1 had an insufficient extent and depth of  
 2 process research and insufficient study  
 3 and understanding of potential genotoxic  
 4 impurities, and as a result, they failed  
 5 to investigate and assess all of the  
 6 reactions, now having seen that, that's  
 7 an important fact that you need to take  
 8 into consideration and reassess your  
 9 opinions as to whether or not they did an  
 10 adequate assessment of the risks of  
 11 formation of nitrosamines, correct?

12          MS. DAVIDSON: Objection.

13          THE WITNESS: So this is a  
 14 draft document. The purpose of a  
 15 draft document is document in  
 16 progress. It's being developed.

17          So if you look at the final  
 18 version, we will see what was  
 19 there.

20          A draft is something which  
 21 is being written by people to be  
 22 considered as a -- as a group, and  
 23 an investigation. In pharma it's  
 24 usually effectively reviewed

1 Control strategy. And the paragraph  
 2 starts, Due to insufficient extent and  
 3 depth of process research at the early  
 4 stage, as well as insufficient study and  
 5 understanding of potential genotoxic  
 6 impurities, only side reaction product  
 7 and degradation products were studied and  
 8 was unaware of the further reaction  
 9 between degradation products and raw  
 10 material.

11          Do you see what I just read?

12          A. Yes.

13          Q. Have you ever seen that  
 14 before right now?

15          A. As I said, this is the  
 16 draft. I've seen the final version.

17          Q. So you've never seen the  
 18 language I just read to you, correct?

19          A. I do not recall reading that  
 20 language in the final version. But it  
 21 may --

22          Q. Now having seen that there  
 23 were people at ZHP that wrote into a  
 24 deviation investigation report that they

1 collectively and it's also  
 2 developed collectively.

3          So because it was in the  
 4 draft, it doesn't mean it's in the  
 5 final version. It doesn't mean  
 6 it's correct.

7          I don't know who wrote that.  
 8 I don't know whether the quality  
 9 organization of the site agreed  
 10 with that statement.

11 BY MR. SLATER:

12          Q. You agree with that  
 13 statement, that that's what occurred?

14          MS. DAVIDSON: Objection.

15          THE WITNESS: This is a  
 16 draft. Let's pull up the final  
 17 version and look --

18 BY MR. SLATER:

19          Q. Let's answer my question.

20          You just said I agree with  
 21 that statement. You're saying you agree  
 22 with the statement I just read to you,  
 23 correct?

24          MS. DAVIDSON: Objection.

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1 That mischaracterizes his  
2 testimony.

3 MR. SLATER: Why are you  
4 testifying? Please don't.

5 MS. DAVIDSON: He didn't say  
6 that.

7 THE WITNESS: No, no.

8 MS. DAVIDSON: You're  
9 misquoting him, Adam.

10 MR. SLATER: Okay. Then  
11 I'll ask you the next question.

12 BY MR. SLATER:

13 Q. You did not say that.

14 You know, one possibility is  
15 that that is true, that's what actually  
16 happened and someone at ZHP said, wait a  
17 second, we can't admit in this document,  
18 which we're submitting to the FDA, what  
19 this says, because it's an admission that  
20 we did insufficient research and an  
21 insufficient risk assessment, so we need  
22 to remove that. That's one possible  
23 reason why that language was removed.

24 You'll -- as an objective

1 correct?

2 If what I just read to you  
3 is actually the truth, they violated  
4 cGMPs, correct?

5 A. If what is written here --  
6 again, I go back, and you're not going to  
7 like my answer, that, effectively, that  
8 development work -- you know, assuming  
9 that's a correct statement, the depth of  
10 process of research at the early stages,  
11 as well as insufficient study and  
12 undertaking, would occur at the  
13 development location where GMPs do not  
14 apply.

15 So, effectively, development  
16 is parceled -- is run at a different  
17 location to the -- to the manufacturing  
18 facility. That's why development has no  
19 GMPs, no -- no rules and regulations  
20 covering it. It's effectively best  
21 practices.

22 Q. Pharmaceutical best  
23 practices?

24 You said "best practices,"

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1 expert, you would agree that's one  
2 possible explanation, right?

3 MS. DAVIDSON: Objection.

4 THE WITNESS: That's -- that  
5 would be against the GMPs of  
6 falsifying records. ZHP was not  
7 cited for data integrity and for  
8 falsifying records.

9 BY MR. SLATER:

10 Q. Did the FDA ever see this  
11 document that I'm showing you right now,  
12 this draft?

13 MS. DAVIDSON: Objection.

14 THE WITNESS: I have no  
15 idea. My point is not whether FDA  
16 saw this draft or not.

17 FDA, if they had been  
18 presented with a draft, if the  
19 investigator would have normally  
20 said, give me the final version,  
21 not the draft.

22 BY MR. SLATER:

23 Q. If what's written there is  
24 actually true, ZHP violated cGMPs,

1 do you mean pharmaceutical best  
2 practices?

3 A. It's the common practice  
4 that development is not regulated by any  
5 regulator.

6 Q. The risk assessment --  
7 rephrase.

8 If the statement I just read  
9 is a true statement in characterizing the  
10 level of research and understanding  
11 during the risk assessment phase of the  
12 change control process, which was  
13 governed by cGMP, then they violated  
14 cGMP, correct?

15 A. If the level of research was  
16 insufficient, it is not contrary to GMPs,  
17 it is just a badly developed process.

18 There are badly developed  
19 processes in pharma, in industry, which  
20 are there.

21 Now, specifically if they  
22 are looking at, okay, we didn't do the  
23 research, or if the statement is a firm  
24 did not do their research to then find

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<sup>1</sup> the formation of degradants and  
<sup>2</sup> degradation products and so on and so  
<sup>3</sup> forth, and informed the regulator that I  
<sup>4</sup> have done the work and everything is fine  
<sup>5</sup> and it's not there, that would be -- in  
<sup>6</sup> fact, not even GMPs, that would be lying  
<sup>7</sup> to the regulator.

<sup>8</sup> Q. The guidances we went  
<sup>9</sup> through earlier talked about the need to  
<sup>10</sup> take every feasible technical effort to  
<sup>11</sup> avoid genotoxic impurities.

<sup>12</sup> Remember we talked about  
<sup>13</sup> that?

<sup>14</sup> A. Yes.

<sup>15</sup> Q. Part of taking every  
<sup>16</sup> feasible technical effort would be making  
<sup>17</sup> sure that you have sufficient extent and  
<sup>18</sup> depth of process research and sufficient  
<sup>19</sup> study and understanding of the potential  
<sup>20</sup> genotoxic impurities so that you could  
<sup>21</sup> understand the potential reactions and  
<sup>22</sup> avoid those reactions and avoid the  
<sup>23</sup> impurity, correct?

<sup>24</sup> A. Yes. On the provision that

<sup>1</sup> 5:42 p.m.  
<sup>2</sup> - - -

<sup>3</sup> (Whereupon, a brief recess  
<sup>4</sup> was taken.)  
<sup>5</sup> - - -

<sup>6</sup> VIDEO TECHNICIAN: We're  
<sup>7</sup> back on the record at 5:42 p.m.

<sup>8</sup> MR. SLATER: Let's put up  
<sup>9</sup> Q7A. We're up to Exhibit-15 now.

<sup>10</sup> - - -  
<sup>11</sup> (Whereupon, Exhibit  
<sup>12</sup> Afnan-15, No Bates, Guidance for  
<sup>13</sup> Industry Q7A Good Manufacturing  
<sup>14</sup> Practice Guidance for Active  
<sup>15</sup> Pharmaceutical Ingredients, was  
<sup>16</sup> marked for identification.)  
<sup>17</sup> - - -

<sup>18</sup> BY MR. SLATER:

<sup>19</sup> Q. Looking at the Q7A, dated  
<sup>20</sup> August 2001, that's a document you're  
<sup>21</sup> familiar with, correct?

<sup>22</sup> A. Yes.

<sup>23</sup> Q. This applied, in your  
<sup>24</sup> opinion, to ZHP's manufacture of

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<sup>1</sup> you expect to form undesirable  
<sup>2</sup> impurities.

<sup>3</sup> MR. SLATER: We can take  
<sup>4</sup> that down.

<sup>5</sup> Let's go -- can you get to  
<sup>6</sup> Q7A by any chance? I'm sorry, I  
<sup>7</sup> didn't give you a heads up, Chris.

<sup>8</sup> Got it? Forget it? Here.

<sup>9</sup> You take it and when you find it  
<sup>10</sup> let me know.

<sup>11</sup> MS. DAVIDSON: Adam, do you  
<sup>12</sup> want to go off the record while  
<sup>13</sup> you figure this out?

<sup>14</sup> MR. SLATER: Nope. I want  
<sup>15</sup> to keep moving, one way or the  
<sup>16</sup> other.

<sup>17</sup> Hey, Chris, can you go to --  
<sup>18</sup> put up the EMEA?

<sup>19</sup> All right. Go off the  
<sup>20</sup> record for a second. I got Chris  
<sup>21</sup> all screwed up with this.

<sup>22</sup> MS. DAVIDSON: No problem.

<sup>23</sup> VIDEO TECHNICIAN: Hang on a  
<sup>24</sup> second. We're off the record at

<sup>1</sup> valsartan?

<sup>2</sup> A. Yes.

<sup>3</sup> Q. Let's go to Page 1.

<sup>4</sup> Under the introduction, the  
<sup>5</sup> second paragraph, the third line, it  
<sup>6</sup> says, In this guidance, the term "should"  
<sup>7</sup> identifies recommendations that, when  
<sup>8</sup> followed, will ensure compliance with  
<sup>9</sup> cGMPs. An alternative approach may be  
<sup>10</sup> used if such approach satisfies the  
<sup>11</sup> requirements of the applicable statutes.

<sup>12</sup> Do you see what I just read?

<sup>13</sup> A. Yes.

<sup>14</sup> Can I ask a question? Is  
<sup>15</sup> there a reason why you're using this  
<sup>16</sup> version?

<sup>17</sup> Q. Is there a different version  
<sup>18</sup> you think I should be using?

<sup>19</sup> A. I'm just asking because  
<sup>20</sup> there is another one which was finalized  
<sup>21</sup> in 2016.

<sup>22</sup> Q. I thought I would use the  
<sup>23</sup> one that was in effect the entire time.

<sup>24</sup> A. Sure. Thank you.

<p style="text-align: right;">Page 386</p> <p>1 Q. Let's go to Page 28.      2 Under the heading of,      3 Laboratory Controls, if we go down to the      4 third paragraph, it says, All      5 specifications, sampling plans and test      6 procedures should be scientifically sound      7 and appropriate to ensure that raw      8 materials, intermediates, APIs and labels      9 and packaging materials conform to      10 established standards of quality and/or      11 purity.</p> <p>12 Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. And ZHP was required to      15 ensure that all of its specifications,      16 sampling plans and test procedures were      17 scientifically sound, right?</p> <p>18 A. Yes.</p> <p>19 Q. That was a cGMP obligation,      20 right?</p> <p>21 A. It is, yes.</p> <p>22 The reason I hesitate is      23 because, actually, since this is a      24 generic drug or generic API, there is a</p>	<p style="text-align: right;">Page 388</p> <p>1 triethylamine, right?      2 MS. DAVIDSON: Objection.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. Correct?</p> <p>5 A. If --</p> <p>6 MS. DAVIDSON: Objection.</p> <p>7 THE WITNESS: If ZHP wanted      8 to sell its product to United      9 States, it would have to meet the      10 requirements of the USP monograph      11 for valsartan.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. And this language I just      14 read, because, remember, we said should,      15 we read that from the beginning, means if      16 you do this, you're going to comply with      17 cGMP.</p> <p>18 And they're saying here, you      19 need to ensure that the raw materials,      20 intermediates, APIs, et cetera, conform      21 to established standards of quality      22 and/or purity, right?</p> <p>23 MS. DAVIDSON: Objection.</p> <p>24 THE WITNESS: It says all</p>
<p style="text-align: right;">Page 387</p> <p>1 USP monograph of valsartan which would      2 actually be the specifications for      3 valsartan.</p> <p>4 Q. We went through, before,      5 that the USP had explained that you must      6 develop additional tests and analytical      7 methods if you change the process and      8 you're going to introduce external      9 sources that could bring impurities into      10 the process.</p> <p>11 Remember we went through      12 that before?</p> <p>13 A. I do remember. That's not      14 the one I'm referring to.</p> <p>15 There is a monograph for      16 valsartan API.</p> <p>17 Q. I realize that.</p> <p>18 But the monograph for      19 valsartan API is not the exhaustive list      20 of tests and acceptance criteria      21 applicable once ZHP developed its new      22 processing methods and was introducing      23 external sources that could bring      24 impurities in, like DMF and</p>	<p style="text-align: right;">Page 389</p> <p>1 specifications, sampling plans,      2 test procedures should be      3 scientifically sound and      4 appropriate to ensure that raw      5 materials, intermediates, APIs and      6 labels and packaging materials      7 conform to standards.</p> <p>8 I'm not disputing that.</p> <p>9 BY MR. SLATER:</p> <p>10 Q. And in this case, it turned      11 out that the -- that the valsartan      12 contained NDMA, and, by definition, the      13 established standards of quality and      14 purity did not approve and allow for NDMA      15 to be in valsartan, correct?</p> <p>16 MS. DAVIDSON: Objection.</p> <p>17 THE WITNESS: So, again, I      18 would like to say that you're --      19 so the monograph on valsartan does      20 not have NDMA. You're correct, it      21 doesn't have it in there.</p> <p>22 But it also stipulates what      23 test methods should be used for --      24 for assessing the specification,</p>

<sup>1</sup> the quality of valsartan.

<sup>2</sup> BY MR. SLATER:

<sup>3</sup> Q. We literally just went  
<sup>4</sup> through this, that non-monograph tests  
<sup>5</sup> and acceptance criteria are required  
<sup>6</sup> where you change the processing methods  
<sup>7</sup> or introduce external sources that could  
<sup>8</sup> bring impurities to them, then you have  
<sup>9</sup> to develop other testing and acceptance  
<sup>10</sup> criteria to address those circumstances.

<sup>11</sup> That's literally what the  
<sup>12</sup> USP says, right?

<sup>13</sup> MS. DAVIDSON: Objection.

<sup>14</sup> THE WITNESS: No. That's  
<sup>15</sup> not what the USP says.

<sup>16</sup> It's if you believe that  
<sup>17</sup> there are undesirable impurities  
<sup>18</sup> present. Q3A allows you to have  
<sup>19</sup> less than .1 percent.

<sup>20</sup> This document, which says  
<sup>21</sup> that it should be scientifically  
<sup>22</sup> sound, Q7, does not address about  
<sup>23</sup> bringing in new test methods or  
<sup>24</sup> whatever. Is --

<sup>1</sup> what you're saying, is it?

<sup>2</sup> A. That's not what I'm saying,  
<sup>3</sup> no.

<sup>4</sup> Q. Okay. And you would agree  
<sup>5</sup> with me the USP did not permit NDMA or  
<sup>6</sup> NDEA to be in the valsartan, correct?

<sup>7</sup> A. USP does not say in its  
<sup>8</sup> monograph NDMA should be absent.

<sup>9</sup> Q. It's understood that there  
<sup>10</sup> should be no NDMA or NDEA in valsartan in  
<sup>11</sup> order to comply with USP, correct?

<sup>12</sup> A. It's understood and accepted  
<sup>13</sup> that nitrosamines should not be present  
<sup>14</sup> in drug product or drug substance at  
<sup>15</sup> levels which cause concern.

<sup>16</sup> Q. Let's go to the next page,  
<sup>17</sup> Page 29.

<sup>18</sup> Section B is, Testing of  
<sup>19</sup> Intermediates and APIs. And the second  
<sup>20</sup> paragraph says, An impurity profile  
<sup>21</sup> describing the identified and  
<sup>22</sup> unidentified impurities present in a  
<sup>23</sup> typical batch produced by a specific  
<sup>24</sup> controlled production process should

<sup>1</sup> BY MR. SLATER:

<sup>2</sup> Q. I --

<sup>3</sup> MS. DAVIDSON: Are you  
<sup>4</sup> interrupting him? Are you done?

<sup>5</sup> THE WITNESS: No, I'm not  
<sup>6</sup> done.

<sup>7</sup> MS. DAVIDSON: You're both  
<sup>8</sup> talking over each other.

<sup>9</sup> THE WITNESS: I'm not done.

<sup>10</sup> So Q7 specifically says,  
<sup>11</sup> here are the specifications, ding,  
<sup>12</sup> ding, ding, ding, specifications,  
<sup>13</sup> sampling plans, test procedures  
<sup>14</sup> should be scientifically sound and  
<sup>15</sup> appropriate.

<sup>16</sup> And what I have said is the  
<sup>17</sup> test procedures are defined by USP  
<sup>18</sup> monograph of valsartan.

<sup>19</sup> BY MR. SLATER:

<sup>20</sup> Q. You're not testifying that  
<sup>21</sup> the USP allows -- rephrase.

<sup>22</sup> You're not testifying the  
<sup>23</sup> USP permitted the valsartan sold by ZHP  
<sup>24</sup> to have NDMA or NDEA in it? That's not

<sup>1</sup> normally be established for each API.

<sup>2</sup> The impurity profile should include the  
<sup>3</sup> identity or some qualitative analytical  
<sup>4</sup> designation, for example, retention time,  
<sup>5</sup> the range of each impurity observed, and  
<sup>6</sup> classification of each identified  
<sup>7</sup> impurity, for example, inorganic,  
<sup>8</sup> organic, solvent.

<sup>9</sup> Do you see that?

<sup>10</sup> A. Yes.

<sup>11</sup> Q. And that requirement applied  
<sup>12</sup> to ZHP and required that they identify,  
<sup>13</sup> in some manner as described here, every  
<sup>14</sup> one of the impurities that were showing  
<sup>15</sup> up on their testing, even if they hadn't  
<sup>16</sup> identified exactly what the impurities  
<sup>17</sup> are, correct?

<sup>18</sup> A. As per text, it says, An  
<sup>19</sup> impurity profile describing the  
<sup>20</sup> identified and unidentified impurities  
<sup>21</sup> present in a typical batch produced by  
<sup>22</sup> specific controls should normally be  
<sup>23</sup> established for each API.

<sup>24</sup> So there should be a purity

<sup>1</sup> and an impurity profile effectively  
<sup>2</sup> created for each product. And this was  
<sup>3</sup> done by ZHP.

<sup>4</sup> Q. Where did ZHP develop an  
<sup>5</sup> impurity profile that identified the NDMA  
<sup>6</sup> and the NDEA in its valsartan in  
<sup>7</sup> accordance with this? Tell me where they  
<sup>8</sup> were identified -- and I'm going to use  
<sup>9</sup> the language, either identified by name  
<sup>10</sup> or some qualitative analytical  
<sup>11</sup> designation.

<sup>12</sup> Tell me where that was done.  
<sup>13</sup> What document did that?

<sup>14</sup> MS. DAVIDSON: Objection.  
<sup>15</sup> THE WITNESS: So if they had  
<sup>16</sup> identified NDMA, which they had  
<sup>17</sup> not, then it would not be listed  
<sup>18</sup> as an unknown -- unidentified  
<sup>19</sup> impurity. ZHP had no cause to  
<sup>20</sup> predict or estimate presence of  
<sup>21</sup> NDMA prior to June 2018.

<sup>22</sup> ZHP did develop an impurity  
<sup>23</sup> profile and -- impurity profile in  
<sup>24</sup> 2007, which was with the TIN

<sup>1</sup> BY MR. SLATER:

<sup>2</sup> Q. In fact, the NDMA and NDEA  
<sup>3</sup> were new impurities that were never  
<sup>4</sup> identified either by name or by some  
<sup>5</sup> qualitative analytical designation  
<sup>6</sup> anywhere in any document.

<sup>7</sup> They never did that, right?

<sup>8</sup> MS. DAVIDSON: Objection.

<sup>9</sup> THE WITNESS: So ZHP, not  
<sup>10</sup> knowing that NDMA or NDEA is  
<sup>11</sup> present in the product, looked at  
<sup>12</sup> the impurity profile, and the  
<sup>13</sup> impurity profile effectively says  
<sup>14</sup> what do you have?

<sup>15</sup> Again, going back to 3A,  
<sup>16</sup> Q3A, it says, you need to list  
<sup>17</sup> your known impurity profile, which  
<sup>18</sup> are listed in the USP monograph,  
<sup>19</sup> and then look at your impurity  
<sup>20</sup> profile and the collective sum of  
<sup>21</sup> those cannot go above a certain  
<sup>22</sup> limit.

<sup>23</sup> So they looked at it; it was  
<sup>24</sup> not there. They didn't see it.

<sup>1</sup> process. Then as they did each  
<sup>2</sup> change, this question was raised,  
<sup>3</sup> addressed and verified that the  
<sup>4</sup> impurity profile has not  
<sup>5</sup> drastically changed, drastically  
<sup>6</sup> changed meaning some -- you know,  
<sup>7</sup> effectively, impurity A  
<sup>8</sup> concentration had gone down as  
<sup>9</sup> they improved the process. The  
<sup>10</sup> impurity profile, it stated, did  
<sup>11</sup> not change.

<sup>12</sup> So both the impurity profile  
<sup>13</sup> and the purity profile remained  
<sup>14</sup> unchanged as they went from the  
<sup>15</sup> TEA process to the zinc chloride  
<sup>16</sup> process.

<sup>17</sup> BY MR. SLATER:

<sup>18</sup> Q. ZHP specifically said that  
<sup>19</sup> the impurity profile had not changed and  
<sup>20</sup> they said that in the DMF for both of the  
<sup>21</sup> new processes, right?

<sup>22</sup> A. Correct.

<sup>23</sup> MS. DAVIDSON: Objection.  
<sup>24</sup> THE WITNESS: Sorry.

<sup>1</sup> They did not know about NDMA or  
<sup>2</sup> NDEA.

<sup>3</sup> BY MR. SLATER:

<sup>4</sup> Q. The peaks -- we'll talk  
<sup>5</sup> about NDMA.

<sup>6</sup> The peak for NDMA was there,  
<sup>7</sup> they just didn't identify what it was.

<sup>8</sup> We've agreed to that before,  
<sup>9</sup> right? You've told me it was too small,  
<sup>10</sup> whatever. But -- let me rephrase.

<sup>11</sup> The NDMA peak was there, it  
<sup>12</sup> just wasn't identified, and it wasn't  
<sup>13</sup> identified by name, and it wasn't  
<sup>14</sup> identified by qualitative analytical  
<sup>15</sup> designation as described in this ICH  
<sup>16</sup> guidance; it was never identified,  
<sup>17</sup> correct?

<sup>18</sup> MS. DAVIDSON: Objection.

<sup>19</sup> BY MR. SLATER:

<sup>20</sup> Q. Either by name or by  
<sup>21</sup> location or anything else?

<sup>22</sup> MS. DAVIDSON: Objection.

<sup>23</sup> That was a lot of questions.

<sup>24</sup> BY MR. SLATER:

1 Q. I'll ask it again, because I  
2 know you got a great objection there.  
3

4 Let's go back to my original  
5 question.

6 Where did ZHP identify the  
7 NDMA and NDEA, either by identity or  
8 qualitative analytical designation, as  
9 required in what I just read?

10 A. ZHP --

11 Q. I've never seen the  
12 document. Is there a document where that  
13 happened?

14 MS. DAVIDSON: Adam,  
15 literally, he started talking and  
16 you asked another question.

17 What are you doing?

18 MR. SLATER: I'm trying to  
19 get him to actually answer my  
20 question.

21 BY MR. SLATER:

22 Q. I'm asking if there's a  
23 document.

24 MR. SLATER: Why don't you  
please ask your witness to just

1 after it had been investigated.

2 They did not report it to  
3 clients unless the clients asked. And  
4 when they did their assessment, which was  
5 based on GC FID and GCMS pointed to a  
6 solvent or solvents that they were using  
7 in the process, not DMF, not any of the  
8 DMF degradants. There are other  
9 processes.

10 And that is in the  
11 communications which went between the  
12 clients and ZHP saying, what was that  
13 impurity?

14 That was also the subject of  
15 my call with Jucai Ge.

16 Q. Nowhere in any impurity  
17 profile have you seen where ZHP  
18 specifically identified each impurity  
19 observed and classified each identified  
20 impurity as required here? That did not  
21 happen, right?

22 MS. DAVIDSON: Objection.

23 THE WITNESS: I've answered  
24 the question. And I'll answer

1 tell me, yes or no, is there a  
2 document where he's seen that.

3 It's the only question I'm asking.

4 THE WITNESS: There was --

5 MS. DAVIDSON: I'm objecting  
6 to this colloquy.

7 Ali, if you know what  
8 question is pending, go ahead and  
9 answer.

10 THE WITNESS: There are  
11 three or four questions there.

12 BY MR. SLATER:

13 Q. I'll ask it again, because  
14 you're confused, you think there's three  
15 or four questions.

16 Is there a document you can  
17 point me to where ZHP identified, either  
18 by name or by qualitative analytical  
19 designation, the NDEA and the NDMA; yes  
20 or no?

21 A. ZHP was not aware of NDMA or  
22 NDEA until June 2018. Prior to June  
23 2018, ZHP had looked at the impurity  
24 profile and the peaks coming, alluding,

1 again.

2 ZHP did not know about NDMA  
3 or NDEA until June 2018. ZHP had  
4 looked at the impurity profile,  
5 and the impurity profile, which  
6 would have been filed with the DMF  
7 changes, would have said what was  
8 there and the fact that the  
9 profile was whatever it was.

10 BY MR. SLATER:

11 Q. And we both know from  
12 reading the DMF that that impurity  
13 profile did not mention NDMA or NDEA or  
14 identify either of those impurities in a  
15 qualitative or quantitative way.

16 They were not mentioned at  
17 all, correct?

18 A. I'll give a repeat.

19 MS. DAVIDSON: Objection.

20 THE WITNESS: ZHP didn't  
21 know about NDMA or NDEA in its  
22 valsartan process until June 2018.  
23 So if it didn't know about the  
24 presence of NDMA or NDEA there was

1 no way for it to actually list  
 2 them as saying, here is NDMA or  
 3 NDEA.

4 It was not expected, it was  
 5 not detected, the methods that  
 6 were there were not sufficient to  
 7 detect them. FDA also agrees with  
 8 that statement.

9 MR. SLATER: You can take  
 10 that document down.

11 BY MR. SLATER:

12 Q. You talked about  
 13 bioequivalence a lot in your report.

14 A. Do you know what that means?

15 A. I hope so.

16 Q. What does bioequivalence  
 17 mean?

18 A. It means it will have the  
 19 same response biologically as the  
 20 reference listed drug.

21 Q. So, for example, with  
 22 valsartan, in simple terms, it will still  
 23 have the desired effect on the body to  
 24 control blood pressure?

1 MR. SLATER: Can I just  
 2 talk, please?  
 3 MS. DAVIDSON: Sure.

4 BY MR. SLATER:

5 Q. Therapeutic equivalent means  
 6 the drug has the same quality, identity  
 7 and purity as the reference listed drug,  
 8 correct?

9 A. Yes.

10 Q. And you understand that our  
 11 claim in this case is not that there was  
 12 a lack of bioequivalence, you understand  
 13 that the claim is that there was a lack  
 14 of therapeutic equivalence?

15 You understand that, right?

16 MS. DAVIDSON: Objection.

17 BY MR. SLATER:

18 Q. Or do you not understand  
 19 that?

20 MS. DAVIDSON: Objection.

21 THE WITNESS: That's -- I  
 22 understand what therapeutic  
 23 equivalence is. I think the  
 24 question of same quality -- the

1 A. The same desired effect as  
 2 its reference listed drug, yes.

3 Q. Therapeutic equivalent is a  
 4 different term with a different meaning,  
 5 correct?

6 A. Yes.

7 Q. That means that the drug has  
 8 the same quality, identity, and purity as  
 9 the reference listed drug, correct?

10 MS. DAVIDSON: Did I freeze  
 11 or did Adam freeze?

12 THE WITNESS: No, you're not  
 13 frozen.

14 BY MR. SLATER:

15 Q. Correct?

16 MS. DAVIDSON: I'm sorry,  
 17 I'm not sure what happened.

18 Did you say something after  
 19 the word "identity"?

20 MR. SLATER: I'll just ask  
 21 the question again.

22 MS. DAVIDSON: Okay. I'm  
 23 sorry. I didn't force my Internet  
 24 to stop.

1 quality, as I said earlier,  
 2 according to USP, is defined to be  
 3 98 to 102 percent purity for  
 4 valsartan.

5 So that's what it means to  
 6 me, 98 to 102 percent.

7 BY MR. SLATER:

8 Q. With all due respect, all  
 9 I'm asking you is this: You used the  
 10 term "bioequivalence," and you said the  
 11 plaintiffs' experts are criticizing the  
 12 lack of bioequivalence. You said that  
 13 many times in your report.

14 Do you understand that the  
 15 claim is not a lack of bioequivalence but  
 16 actually is a claim of a lack of  
 17 therapeutic equivalence?

18 I'm just asking if you  
 19 understand that.

20 MS. DAVIDSON: Objection.

21 THE WITNESS: So your -- the  
 22 plaintiff experts referred to  
 23 bioequivalence. That's what I  
 24 have addressed.

1 You're muted.  
 2

3 MR. SLATER: Can I have the  
 4 court reporter read back the  
 5 answer, please? I lost the feed  
 6 for a second.  
 7 - - -  
 8

9 (Whereupon, the court  
 10 reporter read the following part  
 11 of the record:  
 12

13 "Answer: The plaintiff  
 14 experts referred to  
 15 bioequivalence. That's what I  
 16 have addressed.")  
 17 - - -  
 18

19 BY MR. SLATER:

20 Q. You talked in your report  
 21 about Valisure and testing of Diovan,  
 22 right?

23 A. I did, yes.

24 Q. Are you relying on  
 25 Valisure's testing of Diovan as a basis  
 26 for your opinions in this case?

27 A. Could you just repeat the  
 28 first part? Am I --

1 If we have the NDC number,  
 2 that would directly pinpoint to whether  
 3 it's Diovan or not.

4 Q. I'll let you assume, for  
 5 purposes of these next questions, that  
 6 what Valisure tested was Diovan, okay?

7 A. Okay.

8 Q. If that's the case, are you  
 9 relying on Valisure's testing of Diovan  
 10 purportedly finding NDMA as a basis for  
 11 your opinions? Is it something you're  
 12 relying on as one of the bases for your  
 13 opinions?

14 MS. DAVIDSON: Objection.

15 THE WITNESS: Which opinion?

16 BY MR. SLATER:

17 Q. Any of your opinions.

18 MS. DAVIDSON: The first  
 19 question --

20 BY MR. SLATER:

21 Q. This is really not that  
 22 complicated. I'm not asking for an  
 23 explanation or which opinions. It's a  
 24 very simple question.

1 Q. Are you relying on  
 2 Valisure's purported findings on testing  
 3 of Diovan as a basis for your opinions in  
 4 this case?

5 A. So Diovan -- Valisure tested  
 6 a Novartis product. Novartis in United  
 7 States. That product was the only -- the  
 8 only valsartan which is approved by --  
 9 approved for Novartis is an NDA drug,  
 10 which is listed as a reference standard  
 11 and as the ROD.

12 Valisure tested Novartis  
 13 product. There is no expectation for  
 14 this to be a generic sample which it  
 15 brought to the U.S. and to be tested.  
 16 Valisure tested it, and the plaintiff  
 17 expert lab, Emory, Dr. Najafi, he also  
 18 verified those tests.

19 Now, I believe -- I am not  
 20 certain, but I believe that that Diovan  
 21 was -- or those samples were Diovan.  
 22 I've asked Skadden counsel for the NDC  
 23 number, which has been requested but not  
 24 yet provided.

1 Are you relying on  
 2 Valisure's testing of Diovan and  
 3 purported finding of NDMA in Diovan as  
 4 one of the bases for your opinions in  
 5 this case; yes or no?

6 MS. DAVIDSON: Well, first  
 7 you said assume something. Is the  
 8 assumption still part of your  
 9 question?

10 MR. SLATER: Yes. That they  
 11 tested Diovan.

12 THE WITNESS: So there are  
 13 212 opinions that I have put in.  
 14 I really would need to be very  
 15 careful of saying this applies  
 16 across the board, because, you  
 17 know, some of them have nothing to  
 18 do with Valisure testing. My --

19 BY MR. SLATER:

20 Q. I'll ask you a different  
 21 question.

22 MS. DAVIDSON: Wait. He was  
 23 in the middle of talking.

24 MR. SLATER: Are you just --

1 I'm trying to use time wisely  
 2 here, and you're just wanting to  
 3 just keep talking on something  
 4 like this. I mean, what's the  
 5 point?

6 MS. DAVIDSON: You can't  
 7 interrupt a witness. It's, like,  
 8 Rule 101.

9 MR. SLATER: Maybe you  
 10 should interrupt him.

11 BY MR. SLATER:

12 Q. Keep going, Doctor.

13 A. So my point is that

14 Valisure -- you know, the plaintiff  
 15 experts make the statement saying this  
 16 drug is not equivalent to Diovan.

17 The point is, if Diovan has  
 18 NDMA in it, then what are we talking  
 19 about? Because -- because even Diovan,  
 20 if it had NDMA in it, then you don't --  
 21 that's a discovery which is made late in  
 22 the day.

23 Q. Did you read Dr. Xue's  
 24 deposition?

1 that's significant to you because if  
 2 Diovan had NDMA in it, you said, what are  
 3 we talking about? Do I understand you  
 4 correctly?

5 A. No. My point --

6 Q. Fine. That's fine. I don't  
 7 understand you. Next question.

8 Do you have any

9 understanding or assumption that the  
 10 testing that was performed by Valisure  
 11 was reliable?

12 A. It was verified by the  
 13 plaintiff expert's lab.

14 Q. You're assuming that  
 15 Dr. Najafi's lab actually verified the  
 16 testing of the Diovan that's referred to  
 17 by Valisure; yes or no?

18 A. Dr. Najafi tested the same  
 19 samples, and according to his deposition,  
 20 he said that -- first he said, yes, they  
 21 were the same, and then he said they were  
 22 in the same ballpark.

23 So, no he didn't test for  
 24 Valisure. The results issued or reported

1 A. I did read Dr. Xue's  
 2 deposition.

3 Q. Do you agree with me --  
 4 well, rephrase.

5 Do you agree with Dr. Xue  
 6 that the chemical -- rephrase.

7 Do you agree with Dr. Xue  
 8 that the manufacturing process and the  
 9 chemical reactions in the TIN process  
 10 which is used to make Diovan is not  
 11 capable of forming NDMA?

12 MS. DAVIDSON: Objection.

13 THE WITNESS: Can I see that  
 14 statement from Dr. Xue, please?

15 BY MR. SLATER:

16 Q. No, I don't have time to  
 17 start showing you things. So let me ask  
 18 the question differently.

19 Do you assume, in forming --  
 20 rephrase.

21 If the -- rephrase.

22 If Valisure tested Diovan,  
 23 and if Valisure reported that they found  
 24 NDMA based on that testing, you're saying

1 on Valisure are not necessarily done by  
 2 Emory Labs. But Emory Labs tested and  
 3 agreed with those, according to  
 4 Dr. Najafi.

5 Q. Are you aware that the  
 6 samples that were provided to Dr. Najafi,  
 7 that the results he reported, don't match  
 8 up to the results for the Diovan that was  
 9 tested by Valisure, which shows that he  
 10 actually tested different blind  
 11 specimens?

12 Did you ever look at that  
 13 and match that up?

14 MS. DAVIDSON: Objection.

15 BY MR. SLATER:

16 Q. I'm just asking, did you  
 17 ever look at the results to see that they  
 18 are different?

19 A. His deposition said that  
 20 Valisure told him he is in the right  
 21 ballpark.

22 Q. Did you ever see the letter  
 23 from FDA to Valisure dated December 5,  
 24 2022?

1 A. Yes.

2 Q. Did you see all of the  
3 different problems that the FDA  
4 identified with Valisure's testing,  
5 including their testing for nitrosamine  
6 impurities in valsartan?

7 A. I do -- I prefer -- I would  
8 appreciate if you could show it to me.

9 Q. I'm just asking, do you  
10 remember seeing that the FDA criticized  
11 Valisure's testing for nitrosamine  
12 impurities in valsartan?

13 MS. DAVIDSON: Objection.

14 THE WITNESS: I really would  
15 like to see the document before I  
16 agree to you.

17 BY MR. SLATER:

18 Q. Do you have an opinion that  
19 Valisure's testing was reliable and that  
20 you're relying on what they say about  
21 what they found in Diovan?

22 Just yes or no, I just want  
23 to know.

24 MS. DAVIDSON: Objection.

1 record. Please don't interrupt  
2 me.

3 I was saying if you want --  
4 I was trying to be gracious.

5 MR. SLATER: It's okay.  
6 We're way past gracious, I'm  
7 sorry. I just need to ask my next  
8 question.

9 I don't know why you're  
10 making a face. I just want --

11 MS. DAVIDSON: I just think  
12 it's incredibly rude, Adam, how  
13 you talk over me. Incredibly rude  
14 and shocking.

15 MR. SLATER: I'm sorry, I  
16 don't have a lot of time.

17 MS. DAVIDSON: While I was  
18 offering to go off so that you  
19 wouldn't use your time in looking  
20 at the document.

21 MR. SLATER: I don't need to  
22 look at the document.

23 BY MR. SLATER:

24 Q. Doctor, does the approved

1 He responded multiple times. He  
2 said he wanted to see the letter.

3 You're badgering him and  
4 pressuring him.

5 MR. SLATER: No. What I'm  
6 doing is not getting all my time  
7 sucked up to show him something  
8 that he already knows.

9 THE WITNESS: I have not  
10 looked at Valisure's document --

11 BY MR. SLATER:

12 Q. Okay. I'll --

13 A. No, no, no.

14 I have not looked at  
15 Valisure's GMP systems to make a decision  
16 whether it's reliable or not.

17 Q. Okay.

18 A. Sorry.

19 MS. DAVIDSON: If you want  
20 him to look at the letter --

21 MR. SLATER: No, I really  
22 don't. I'm going to ask my next  
23 question.

24 MS. DAVIDSON: -- off the

1 formulation of Diovan include NDMA in it?

2 A. Approved formulation? Can  
3 you be very specific?

4 Do you mean what FDA  
5 approved or do you mean what is being  
6 sold in the market?

7 Q. What FDA approved.

8 A. So what FDA approved should  
9 not have -- actually, I have no idea,  
10 because now it's hindsight. We are  
11 looking back.

12 At the time FDA approved,  
13 FDA assumed there was no NDMA. At the  
14 time FDA approved ZHP process, there was  
15 an understanding that there was no NDMA.

16 Q. If there would be NDMA in a  
17 Diovan pill, that would be due to a cGMP  
18 violation in the manufacturing process,  
19 correct?

20 MS. DAVIDSON: Objection.  
21 Calls for speculation.

22 THE WITNESS: I can't make  
23 that statement. You know, you  
24 want a yes-or-no answer, and I'm

<p>1 sorry, I can't give you a 2 yes-or-no answer.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. Are you aware that the 5 manufacturing process and chemical 6 reactions for Diovan are incapable of 7 forming NDMA as an impurity?</p> <p>8 MS. DAVIDSON: Objection.</p> <p>9 THE WITNESS: I have not 10 looked at the NDMA process. I am 11 looking at Valisure. I am looking 12 at, effectively, Dr. Najafi saying 13 that, yes, he found it and it's in 14 the -- ballpark agrees with 15 Valisure's data.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. If I'm correct and Dr. Xue 18 is correct that the manufacturing process 19 for Diovan was not capable of creating 20 NDMA, then the only way for NDMA to get 21 into the pills would be due to a cGMP 22 violation, correct?</p> <p>23 A. I cannot --</p> <p>24 MS. DAVIDSON: Same</p>	<p>Page 418</p> <p>1 BY MR. SLATER: 2 Q. We've put on the screen 3 Exhibit-16, a genotoxicity statement, 4 dated July 14, 2015, signed by Lucy Liu, 5 manager of regulatory affairs at ZHP. 6 Have you seen this document? 7 A. I think I have. 8 Q. And you can see on July 14, 9 2015, ZHP represented that its valsartan 10 was, to the best of its knowledge, in 11 accordance with the guideline, the 12 EMEA/CHMP/QWP/251344/2006 and ICH M7. 13 Do you see that? 14 A. Yes. 15 Q. Do you know what the first 16 guideline is that they listed there? 17 A. It's the quality working 18 party of EMEA. 19 Q. What's the significance of 20 that guideline? 21 A. That -- 22 MS. DAVIDSON: Objection. 23 THE WITNESS: Yes. 24 So can we pull it up,</p>
<p>1 objections.</p> <p>2 THE WITNESS: I cannot 3 comment on Novartis's 4 manufacturing process because I 5 have not looked at it. I don't 6 know what they do.</p> <p>7 You obviously have knowledge 8 of the process. I don't.</p> <p>9 MR. SLATER: Let's go off 10 the record.</p> <p>11 VIDEO TECHNICIAN: We're off 12 the record at 6:14 p.m.</p> <p>13 - - -</p> <p>14 (Whereupon, a brief recess 15 was taken.)</p> <p>16 - - -</p> <p>17 VIDEO TECHNICIAN: We're 18 back on the record at 6:22 p.m.</p> <p>19 - - -</p> <p>20 (Whereupon, Exhibit 21 Afnan-16, ZHP01721348, 22 Genotoxicity Statement, was marked 23 for identification.)</p> <p>24 - - -</p>	<p>Page 419</p> <p>1 please?</p> <p>2 BY MR. SLATER:</p> <p>3 Q. I don't have that. I've 4 never seen it. I don't even know what it 5 is.</p> <p>6 A. Okay. So this is EMEA. 7 This is very old, because they are no 8 longer called EMEA.</p> <p>9 And what they did was they 10 actually, I think, and I'm not sure, so 11 I'm speculating here, that that was the 12 precursor to M7.</p> <p>13 Q. They say that this is -- 14 rephrase.</p> <p>15 They say that the valsartan 16 is in accordance with ICH M7.</p> <p>17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. So based on this document, 20 ZHP was applying ICH M7 as of July 14, 21 2015, correct?</p> <p>22 MS. DAVIDSON: Objection. 23 THE WITNESS: I'm sorry, but 24 it doesn't say that.</p>

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<sup>1</sup> BY MR. SLATER:

<sup>2</sup> Q. They're making a  
<sup>3</sup> genotoxicity statement and they're  
<sup>4</sup> representing that the valsartan complies  
<sup>5</sup> with ICH M7.

<sup>6</sup> That's what the document  
<sup>7</sup> says, right?

<sup>8</sup> A. It says that the drug  
<sup>9</sup> substance valsartan manufactured by this  
<sup>10</sup> is, to the best of our knowledge, in  
<sup>11</sup> accordance with M7, yes.

<sup>12</sup> Q. They then say, The reagents,  
<sup>13</sup> intermediates and impurities susceptible  
<sup>14</sup> of generating genotoxic impurities have  
<sup>15</sup> been taken into account. No genotoxic  
<sup>16</sup> impurities are present in the substance.

<sup>17</sup> Do you see that?

<sup>18</sup> A. Yes.

<sup>19</sup> Q. In retrospect, that  
<sup>20</sup> statement was incorrect, because we know  
<sup>21</sup> that there were genotoxic impurities in  
<sup>22</sup> the valsartan, correct?

<sup>23</sup> MS. DAVIDSON: Objection.

<sup>24</sup> THE WITNESS: In 2023 and in

1

MS. DAVIDSON: Let's go off  
<sup>2</sup> the record.

<sup>3</sup> VIDEO TECHNICIAN: We're off  
<sup>4</sup> the record at 6:25 p.m.  
<sup>5</sup> - - -

<sup>6</sup> (Whereupon, a brief recess  
<sup>7</sup> was taken.)  
<sup>8</sup> - - -

<sup>9</sup> VIDEO TECHNICIAN: We're  
<sup>10</sup> back on the record at 6:34 p.m.  
<sup>11</sup> MS. DAVIDSON: Great.  
<sup>12</sup> - - -

<sup>13</sup> EXAMINATION  
<sup>14</sup> - - -

<sup>15</sup> BY MS. DAVIDSON:

<sup>16</sup> Q. Dr. Afnan, it's late in the  
<sup>17</sup> evening. I just have a few very quick  
<sup>18</sup> questions for you.

<sup>19</sup> My first question is,  
<sup>20</sup> earlier today there was some discussion  
<sup>21</sup> of the DMF --

<sup>22</sup> A. You froze.

<sup>23</sup> Q. -- is that correct?

<sup>24</sup> A. Sorry. You cut out.

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<sup>1</sup> post June 2018, yes, we know.

<sup>2</sup> Pre June 2018, ZHP didn't  
<sup>3</sup> know.

<sup>4</sup> MR. SLATER: All right. I'm  
<sup>5</sup> not going to ask any other  
<sup>6</sup> questions at this point.

<sup>7</sup> I'm reserving whatever  
<sup>8</sup> minutes I have left. And  
<sup>9</sup> depending on how many questions  
<sup>10</sup> counsel asks, I will intend to  
<sup>11</sup> continue to ask reasonable  
<sup>12</sup> follow-up questions.

<sup>13</sup> And I'm reserving all my  
<sup>14</sup> rights regarding whether or not I  
<sup>15</sup> need to ask for more time in the  
<sup>16</sup> future.

<sup>17</sup> So I'm handing it off to  
<sup>18</sup> defense counsel.

<sup>19</sup> MS. DAVIDSON: Thank you,  
<sup>20</sup> Adam. I will just have very few  
<sup>21</sup> questions. I need five minutes  
<sup>22</sup> first.

<sup>23</sup> VIDEO TECHNICIAN: Would you  
<sup>24</sup> like to go off the record?

<sup>1</sup> Can you repeat?

<sup>2</sup> MS. DAVIDSON: I went back  
<sup>3</sup> upstairs. Okay. It's clearly an  
<sup>4</sup> upstairs/downstairs thing. Can  
<sup>5</sup> you guys hear me now?

<sup>6</sup> BY MS. DAVIDSON:

<sup>7</sup> Q. So I said that earlier today  
<sup>8</sup> I believe there was some discussion of  
<sup>9</sup> the DMF for the zinc chloride process,  
<sup>10</sup> and you testified that the DMF is still  
<sup>11</sup> active; is that correct?

<sup>12</sup> A. The drug master file is  
<sup>13</sup> still active, yes.

<sup>14</sup> Q. Do you know whether there  
<sup>15</sup> have been any changes to that drug master  
<sup>16</sup> file over time?

<sup>17</sup> A. Yes.

<sup>18</sup> Q. And when I say do you know  
<sup>19</sup> if there have been, maybe that wasn't a  
<sup>20</sup> great question.

<sup>21</sup> Have there been --

<sup>22</sup> A. Yes.

<sup>23</sup> Q. -- changes in the drug  
<sup>24</sup> master file over time?

<sup>1</sup> A. Yes, there have been changes  
<sup>2</sup> to the DMF.

3 Q. Okay. My other question for  
4 you was, earlier today we talked about a  
5 WHO document.

6 MS. DAVIDSON: And can we  
7 bring that document back on the  
8 screen? Unfortunately, I don't  
9 remember what exhibit number it  
10 was.

11 We can either reintroduce it  
12 or -- Chris, do you know what  
13 document that was? The WHO  
14 document, Chris Geddis, master of  
15 the documents?

16 MR. SLATER: He sort of  
17 checked out on this thing. He was  
18 working on other stuff.

19 MS. DAVIDSON: He's not  
20 here?

21                   MR. SLATER: He's here, but  
22 he moved on to some other work.

23

Exhibit-6

<sup>24</sup> MS. DAVIDSON: Okay.

everybody.

**VIDEO TECHNICIAN:** If there's nothing further, the time is now 6:37 p.m., this concludes today's testimony from Dr. Ali Afnan. We are now off the record.

(Whereupon, the deposition concluded at 6:37 p.m.)

<sup>1</sup> BY MS. DAVIDSON:

<sup>2</sup> Q. Dr. Afnan, if you could -- I  
<sup>3</sup> believe you have Exhibit-6 in your files.  
<sup>4</sup> I just want to make sure you know which  
<sup>5</sup> document we're talking about.

<sup>6</sup> A. Yes. It's the -- it's the  
<sup>7</sup> WHO document 2001.

8 Q. I just wanted to clarify, do  
9 you -- looking at this document, do you  
10 know when you first saw it?

<sup>11</sup> A. Actually, I made a mistake,  
<sup>12</sup> I think because it looks familiar

13 This was presented in -- I  
14 saw this after my report. This was  
15 present in Dr. Bain's testimony as one of  
16 the exhibits of her testimony. So I have  
17 not seen it prior to writing my report.

18 MS. DAVIDSON: Those are my  
19 only questions.

THE WITNESS: I apologize.

21 MR. SLATER: No other  
22 questions.

23 MS. DAVIDSON: Enjoy your  
24 dinner Adam. Have a good night

**CERTIFICATE**

I, Amanda Maslynsky-Miller, Certified  
Realtime Reporter, do hereby certify that  
prior to the commencement of the examination,  
ALI AFNAN, Ph.D., was remotely sworn by me to  
testify to the truth, the whole truth and  
nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by me at the time, place and on the date hereinbefore set forth, to the best of my ability.

<sup>1</sup> I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor  
<sup>2</sup> counsel of any of the parties to this action, and that I am neither a relative nor employee  
<sup>3</sup> of such attorney or counsel, and that I am not financially interested in the action.

Amanda Miller  
Certified Realtime Reporter  
Dated: February 10, 2023

<sup>0</sup> (The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the <sup>1</sup> direct control and/or supervision of the certifying reporter.)

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1           **INSTRUCTIONS TO WITNESS**

2  
3           Please read your deposition  
4 over carefully and make any necessary  
5 corrections. You should state the reason  
6 in the appropriate space on the errata  
7 sheet for any corrections that are made.

8           After doing so, please sign  
9 the errata sheet and date it.

10          You are signing same subject  
11 to the changes you have noted on the  
12 errata sheet, which will be attached to  
13 your deposition.

14          It is imperative that you  
15 return the original errata sheet to the  
16 deposing attorney within thirty (30) days  
17 of receipt of the deposition transcript  
18 by you. If you fail to do so, the  
19 deposition transcript may be deemed to be  
20 accurate and may be used in court.

21

22

23

24

1           **ACKNOWLEDGMENT OF DEPONENT**

2  
3           I, \_\_\_\_\_, do  
4 hereby certify that I have read the  
5 foregoing pages, 1 - 428, and that the  
6 same is a correct transcription of the  
7 answers given by me to the questions  
8 therein propounded, except for the  
9 corrections or changes in form or  
10 substance, if any, noted in the attached  
11 Errata Sheet.

12          ALI AFNAN, Ph.D.      DATE

13          Subscribed and sworn  
14 to before me this  
15         \_\_\_\_ day of \_\_\_\_\_, 20 \_\_\_\_.

16          My commission expires: \_\_\_\_\_

17          Notary Public

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2           **E R R A T A**

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1           **LAWYER'S NOTES**

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